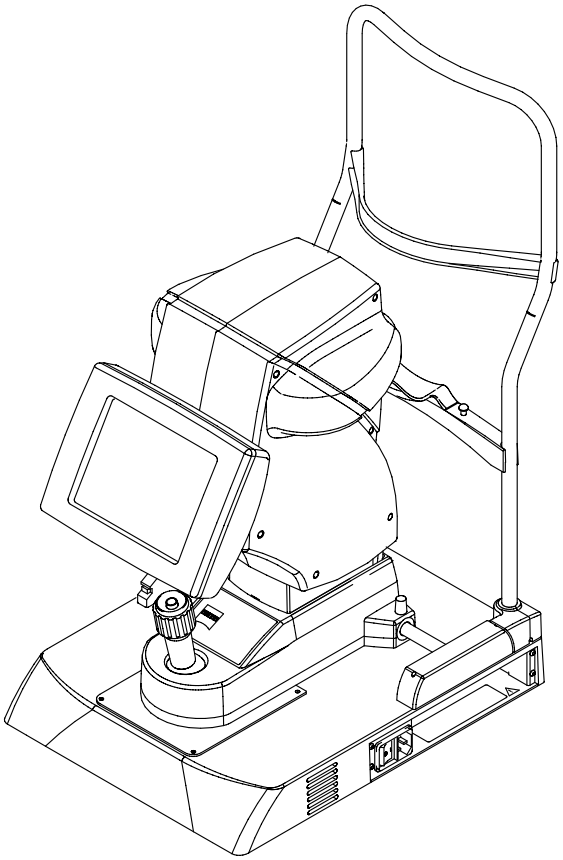
IOLMaster

with Advanced Technology
Software Release 5.xx



User manual

ZEISS

Copyright

Knowledge of this user manual is required for operation of the device. You should therefore familiarise yourself with the contents of this manual and pay special attention to instructions concerning the safe operation of the device.

The specifications are subject to change; the manual is not covered by an update service.

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Symbols

The following warning symbols refer to important safety information in this user manual. Whenever you see these symbols, read the accompanying notes carefully. They may warn against possible health risks or mortal danger.
Observe all safety notes and information in this manual and on device labels.

	**Warning**	Risk to the user or patient.
	**Caution**	Risk of damage to the device.
	Type B medical device conforming to DIN EN 60601-1	
	**Caution**	Disconnect the device from the power supply before servicing.
	**Note**	Information and notes for a better understanding of the operating instructions.



Warning
Correct operation of the device is imperative for safe functioning. Please familiarise yourself thoroughly with the contents of this user manual before using the device.

Purpose of this documentation

The purpose of this user manual is to acquaint the user with the design, operation, setup, handling of the device together with the safety, cleaning and maintenance procedures for the system.

Accessibility of the user manual

Always keep this user manual and all accompanying documents in the immediate vicinity of the device. The user manual should be readily accessible at all times.

Compliance with standards and regulations

- ❑ This device is a Class IIa medical instrument as defined by the European Medical Device Directive (MDD).
- ❑ This device complies with EC Medical Device Directive 93/42/EEC and the national implementation of this directive in the form of the German Medical Products Act (see *Manufacturer's Declaration* on page 114).

Instructions for installation and use

This device is a high-quality technical product. To ensure perfect and reliable operation, it must undergo a safety inspection once a year.

- ❑ The device may not be stored or operated in environmental conditions other than those prescribed (see *Technical specifications* on page 109).
- ❑ Do not operate the device:
  - in areas subject to explosion hazard
  - in the presence of inflammable anaesthetics or volatile solvents, such as alcohol, benzene or similar.
- ❑ Do not store or use this device in damp rooms. Do not expose the device to water splashes, dripping water or sprayed water.
- ❑ Modifications and repairs, in particular those requiring the device to be opened, may only be performed by service technicians employed or authorised by the manufacturer.
- ❑ The manufacturer accepts no liability for damage caused by unauthorised access to the interior of the device. Such actions will render all warranty claims invalid.
- ❑ This device may only be used with accessories and software supplied by Carl Zeiss Meditec. Mains-operated accessories must conform to IEC 60950-1 or 60601-1.
- ❑ The device may only be operated by instructed and trained personnel.
- ❑ In USA this device may only be purchased or ordered by physicians and ophthalmologists.
- ❑ The user manual should always be kept at hand for reference.
- ❑ It is also important to comply with the instructions supplied with accessories.

❏ Use only printers approved by Carl Zeiss Meditec.
- Use only the CD supplied by the printer manufacturer to install the printer software.
- Prior to using older printers, consult http://support.microsoft.com/ to determine whether printer drivers compatible with the Windows®XP operating system are available and use these.
- Position the printer at least 1.5 m from the patient's seat at the device.
- The user should not simultaneously touch the patient and metal parts of the printer.
- If a Protection Class II printer (without protective earth terminal) is used, make sure that a power isolation transformer (see page 17) is connected into the printer power supply cable.
- If a Protection Class I printer (with protective earth terminal) is used, make sure that it is connected to its own stationary wall socket of the room's electrical installation or that a power isolation transformer (see page 17) is connected into the printer power line.
  The required isolation transformer can be obtained from our sales organisation.
- The power isolation transformer may not be used for printers whose wattage (power consumption) exceeds the permissible connected load of the power isolation transformer (e.g. laser printers). Such printers must always be positioned outside the range of the patient (1.5 m from the patient's seat at the device).
- Protection Class II printers (without protective earth terminal) whose wattage (power consumption) exceeds the permissible connected load of the power isolation transformer may not be used.



❏ Additional portable multiple sockets or extension cords may not to be used.

❏ The electrical supply must conform to IEC 60364-7-710 guidelines. For USA and Canada only: Single-phase 120 V AC connectors with NEMA 5-15P connector type.

❏ Do not use a cellular telephone and other devices not complying with EMC Class B requirements, as its signals may cause the equipment to malfunction. The effect of radio signals on medical devices is dependent on various factors and therefore unpredictable. To avoid electromagnetic interference, the device must be installed and put into operation in accordance with the user manual and using the components supplied by Carl Zeiss Meditec.

❏ With the exception of compatible printer drivers, the installation of other software on the system is not permitted! A software routine prevents external (third party) software from being installed on the system.

❏ The IOLMaster may only be connected to private networks which are protected from public networks (Internet) by firewalls conforming to the latest technical standards!

Safe operation

Electrical safety

- ❑ The built-in power supply unit is short-circuit-proof and does not contain any fuses which are accessible from the outside.
- ❑ Provided the device is properly used, no electrical hazards exist to either patients or operators.
- ❑ The device may be opened only by persons authorised by the manufacturer.

Light emission from the device

The limit values as specified for Class 1 laser devices to EN 60825-1 will be observed if the device is operated as intended.



Requirements for operation

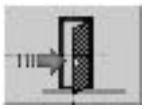
Please take care that the following operational requirements are met when using the IOLMaster:



- ❑ Use the power cable supplied with the device. If the device is mounted on an IT3L instrument table, it will receive its power supply through the table.
- ❑ The power supply plug must be inserted into a power outlet that has an intact protective conductor connection.
- ❑ All cables and plugs may be used only if they are in perfect working condition. In particular, the spring action plug for device control (**7**, Fig. 3) must remain plugged in and should not be pulled out.
- ❑ If the earth contact is impaired, or if electrical wiring is damaged, the device must be taken out of service and measures taken to prevent inadvertent use. Following this, call Carl Zeiss Service.
- ❑ Do not cover/obstruct ventilation slots in the computer casing (right and left)!
- ❑ If peripheral devices are connected (CRT monitor and/or PC are possible) the user must ensure that safety requirements of DIN EN 60601-1-1 (medical electrical systems) are observed.
- ❑ A network isolator can be ordered from Carl Zeiss for connection to an external network (NET).
- ❑ If either of the error messages "Laser adjustment too high" or "Laser power measurement too high, measurement aborted" appears, the device must be shut down.
  Following this, call Carl Zeiss Service.

Important when using the device

- ❑ Always enter the patient data (last and first name, date of birth) or ID No. (depending on setting in **Setup** menu).
- ❑ Pull the power supply cable immediately if damage or unspecified problems occur!



- ❑ Switch off the device as follows:
  - Click on the ***EXIT*** icon on the toolbar.
  - Confirm with ***OK*** and switch the device off at the power switch. The program will automatically close; the readings for the last patient will be saved and the device will shut down automatically (lamp in the switch goes off).



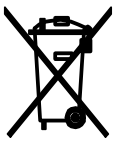
Caution
For as long as the switch lamp is lit, internal components are still under voltage, even after the device has been switched off at the power switch! All-pole disconnection of the device has not been achieved until the switch lamp goes off. The lamp must be off before the power supply is unplugged or the device switched off at the main room switch. Failure to observe these instructions may result in loss of data.

- ❑ The device contains a computer. Please follow the instructions for the *Switching off the device* on page 74.

Disposal

The device's internal control computer contains electronic components and a lithium battery (type CR 2032). At the end of its useful life it must be properly disposed of in compliance with local regulations.

Disposal of the product within the EU



In accordance with applicable EU guidelines at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

For further information on disposal of this product, please contact your local dealer or the manufacturer or its legal successor company. Please read the latest internet information provided by the manufacturer.

Where the product or its components are resold, the seller must inform the buyer that the product must be disposed of in accordance with the currently applicable national regulations.

Package contents

The device is delivered completely assembled in foam material packaging. The enclosed accessory box contains the following components:

- Keyboard
- Power cable
- This user manual
- Dust cover
- Test eye in its own case
- 2x CD/RW (formatted)

Save the original packaging for storing the device during extended periods of non-use or returning it to the manufacturer, or dispose of it properly.

Warning and information labels on the device

The device casing carries the following warning and information labels:

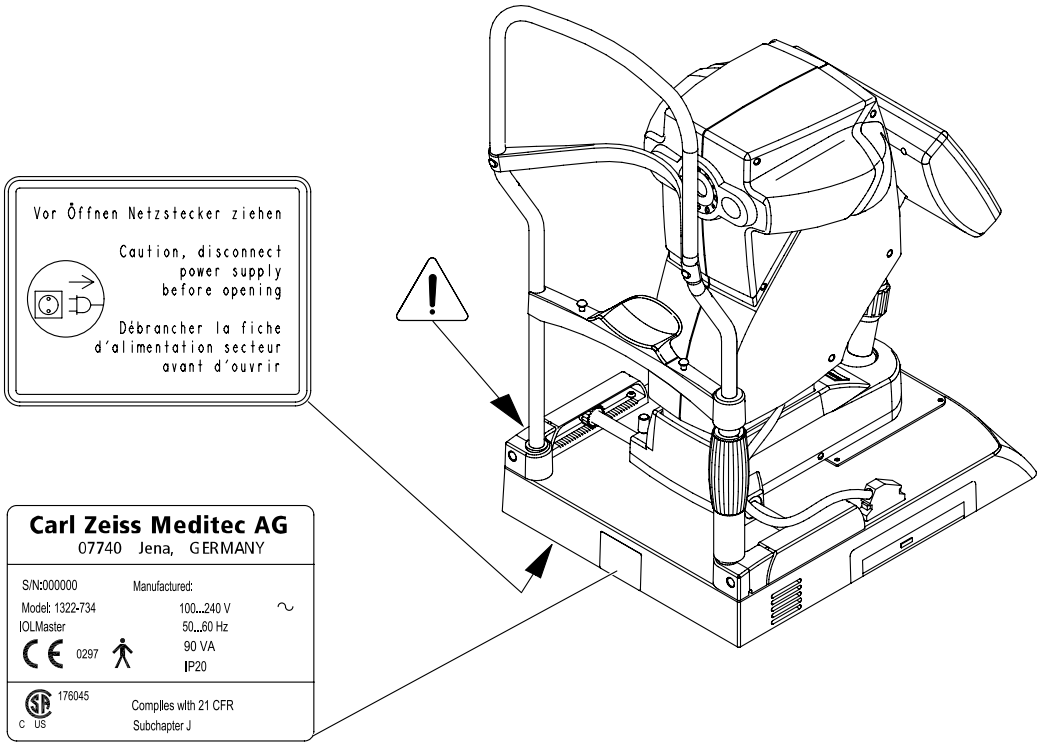


Fig. 1 Warning and information labels on the device

Customer's safety obligations

The user is responsible for ensuring that:

- ❑ the device is used in accordance with the instructions provided in this manual.
- ❑ deviations from the target refraction are precluded by proper handling of the device:
  - Patient must fixate correctly
  - Device must be precisely focused for keratometry or anterior chamber depth measurements.
  - Biometry formulae must be properly used
  - Only adjusted IOL constants may be used
- ❑ the device is only used in a perfect operating condition without functional impairment.
- ❑ the user manual and all accompanying documents are maintained in good condition and kept on or in the immediate vicinity of the device.
- ❑ only sufficiently trained and authorised personnel is permitted to operate, maintain and repair the device.
- ❑ all operating personnel receives regular instruction on all issues concerning the device and its components, that such persons are familiar with the user manual and, in particular, the safety precautions.
- ❑ none of the warning signs on the system are removed or rendered illegible.
- ❑ the device is inspected according to *Checking the measurement functions* on page 104 before any patient measurements are taken.
- ❑ each day no more than 20 axial length measurements are taken on each patient's eye.
- ❑ a safety inspection is performed on the device each year (see page 108) in order to guarantee its perfect operating condition.

Intended use of the device

The device is to be used only for the measurement of axial length, corneal radii, anterior chamber depth and optionally for the determination of "white-to-white" of the human eye, as well as for the calculation of the required intraocular lens. Responsibility for using the device other than as intended lies with the user.
The device may only be used in combination with accessories delivered by Carl Zeiss Meditec (see Section *Optional accessories* on page 16). Please consult Carl Zeiss Service regarding the use of other accessories.

Functional description

The IOLMaster is a combined biometry device for measurements on the human eye required for the preoperative computation of intraocular lens power.

It is capable of fast and precise consecutive measurement of the following eye parameters in one session: axial length, corneal curvature, anterior chamber depth and optionally "white-to-white". All measurements are non-contact, providing excellent patient comfort.

The axial length measurement is based on a patented interference optical method known as partial coherence interferometry (PCI). The displayed results of the axial length measurements are compatible with the ultrasonic immersion measurements of axial length via the use of an internal, statistically verified calculation algorithm. The familiar formulae for IOL calculation can thus be used.

However, the lens constants must be changed for use with the PCI method. Please consult the scientific literature on this subject.

The corneal curvature is determined by measuring the distance between reflected light images projected onto the cornea.

The anterior chamber depth is determined as the distance between the optical sections of the crystalline lens and the cornea produced by lateral slit illumination.

"White-to-white" is determined from the image of the iris.

The individual measurement procedures are automated, so that the operator is only required to adjust the device to the patient's eye and initiate the measurement. For this reason the complex biometry of the eye can be rapidly learnt with the IOLMaster, but should be practised with the greatest of care and attention to detail.

Extensive integrated safety features (independent redundant hard and software safety features) ensure maximum safety for both the patient and operator when using the IOLMaster.

The control program for the computer in the device base runs under Windows. A backlit LCD serves to observe the patient's eye and display

the readings. The device is controlled by the joystick and computer keyboard with integrated touchpad.

Based on the readings, the program can make suggestions for the choice of intraocular lens strengths. The latter are based on internationally accepted calculation formulae. The Haigis, HofferQ, Holladay, SRK II and SRK/T formulae are implemented in the software.[1]

The Haigis-L formula may be used to calculate IOLs after myopic LASIK/PRK.[1]

The refractive history or contact lens method may be used to correct the measured corneal radii/refraction following refractive corneal surgery.[1]

Selected phakal implants may be calculated by the "calculation for phakic implants".[1]

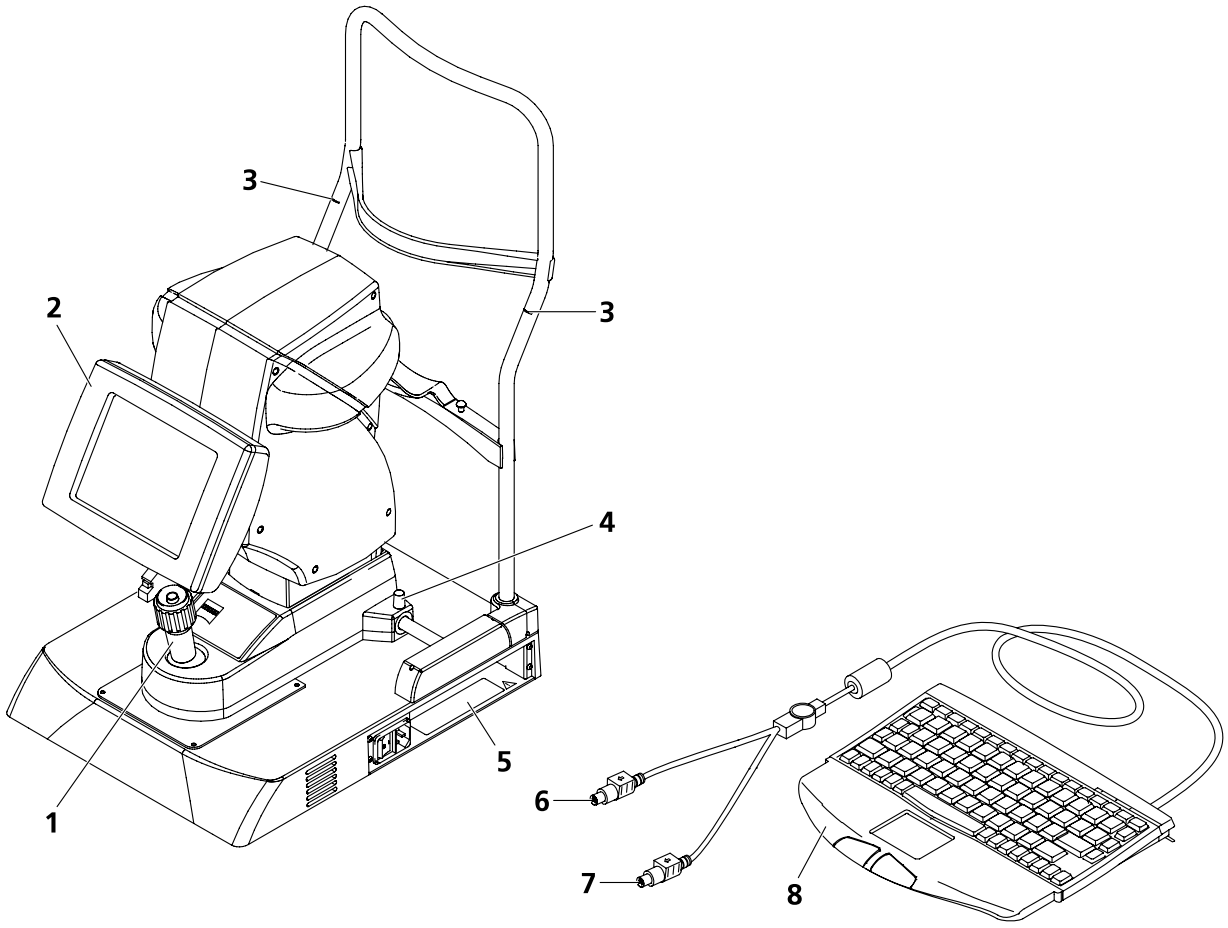
An IOL database is likewise implemented. Prior to calculation, the latter must be filled with data for the desired lens.

On the basis of postoperative refraction results, the lens constants entered into the calculation formulae may be optimised (personalised) for each individual user.

[1] Literature on the formulae (in case of specific questions please contact Carl Zeiss Meditec):

- Haigis:
  http://www.augenklinik.uni-wuerzburg.de/uslab/ioltxt/haid.htm
- HofferQ:
  HOFFER KJ: The Hoffer Q formula: A comparison of theoretic and regression formulas. J Cataract Refract Surg, 19:700-712, 1993; ERRATA 20:677, 1994
- Holladay:
  HOLLADAY JT, PRAGER TC, CHANDLER TY, MUSGROVE KH, LEWIS JW, RUIZ RS: A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg, 14:17-24, 1988
- SRKII:
  RETZLAFF J: A new intraocular lens calculation formula, Am Intra-Ocular Implant Soc J 6:148-152, 1980
- SRK/T:
  RETZLAFF J, SANDERS DR, KRAFF MC: Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 16 (3):333-340, 1990
- Haigis L:
  HAIGIS W: Publication in preparation
- Correction of corneal radii/corneal refraction after corneal refractive surgery:
  HOLLADAY JT: IOL calcualtions following RK. Refract Corneal Surg 5(3):203, 1989
  HOFFER KJ: Intraocular lens power calculation for eyes after refractive keratotomy. J Refract Surg 11:490:493, 1995
- Calculation of phakic implants:
  vd HEIJDE GL, FECHNER PU, WORST JGF: Optische Konsequenzen der Implantation einer negativen Intraokularlinse bei myopen Patienten. Klin MB1 Augenheilk 192:99-102, 1988
  HOLLADAY JT: Refractive power calculations for intraocular lenses in the phakic eye. Am J Ophthalmol 116:63-66, 1993
  HAIGIS W: Biometry in complicated situations, 9th Conv. of DGII 1995, Rochels et al (Hrsg.), Springer, 17-26, 1996

Overall view



1 Joystick with release button
for adjusting the measuring device horizontally (X, Y) and vertically (Z, by turning)

2 Display
Patient eye alignment and display of results

3 Red eye level marks
patient eye level needed for optimum measurement

4 Instrument lock knob

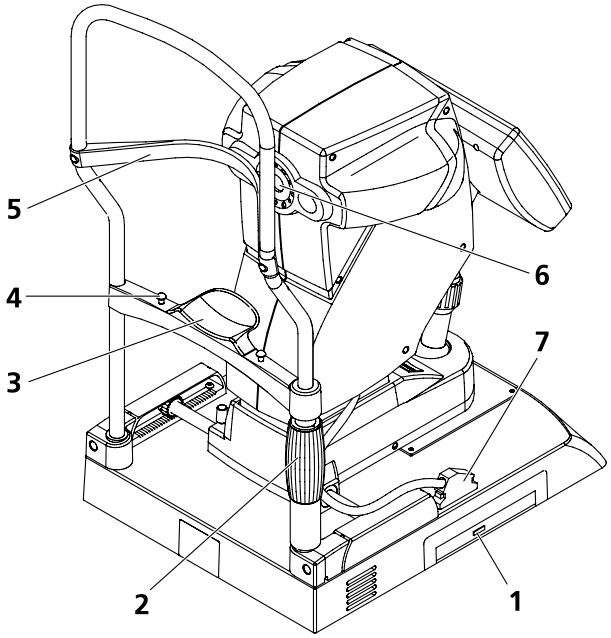
5 Connector panel (see also Fig. 9)

6 Mouse connector (light green)

7 Keyboard connector (purple)

8 Keyboard (see also Fig. 10)
Optional: Printer (not shown)

Fig. 2 View from doctor's side



1 DVD drive/CD-RW drive
for data storage and software installation
2 Adjustment of headrest
3 Patient chin rest
4 Holding pins for paper pads
also used to test eye alignment
5 Patient forehead rest
6 Aperture for semiconductor diode laser (MMLD)
7 Device control connector

Fig. 3 View from patient's side

Optional accessories

- ❏ Instrument table IT 3L
- ❏ Holding bar for securing the IOLMaster on the instrument table
- ❏ Printer
- ❏ Keyboard support
- ❏ Narrow holding bracket for securing the IOLMaster on the keyboard support
- ❏ Paper pads for patient chinrest
- ❏ Power isolation transformer for connection of external accessory units
- ❏ Network isolator
- ❏ Software option A plus
- ❏ Software option B
- ❏ Connecting cable for coupling with PC

Power isolation transformer for external devices

Warning

Always connect all peripheral devices, printers and monitors to the power isolation transformer.

No components other than those prescribed for the system may be connected to the power isolation transformer or instrument table. Non-compliance represents a violation of the regulations for use of medical devices under DIN EN 60601-1-1.

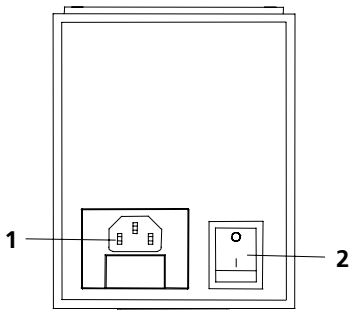
Likewise excepted are laser printers, as their rated supply voltage usually exceeds the permissible connected load of the power isolation transformer. Position the laser printer outside the patient's range (1.5 m from the patient's seat at the device).

If the Carl Zeiss IT 3L instrument table is used, the power isolation transformer may be mounted to the underside of the tabletop. It may be secured elsewhere, but not placed on the floor.

Warning

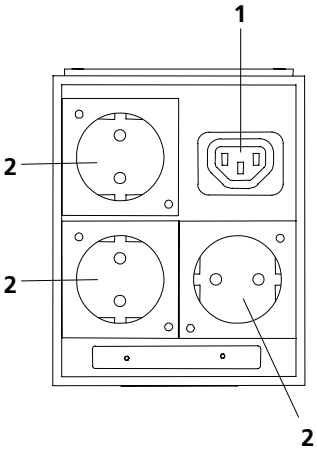
The IOLMaster should **never** be operated via the power isolation transformer!

The power isolation transformer is not a constituent part of the IOLMaster.



1 Power cable connector with fuses
2 Power switch

Fig. 4 Power isolation transformer, input side



1 Instrument connector
2 Power junction connector

Fig. 5 Power isolation transformer, output side 230 V

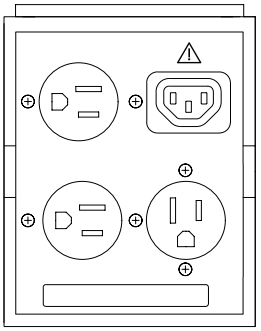


Fig. 6 Power isolation transformer, output side 120 V

Setting up the device for use

The device must be set up and commissioned by authorised representatives of Carl Zeiss; the latter will also instruct the users on operation of the device.

In general, Carl Zeiss Service will perform the following operations.

Installation

❑ Remove and unpack box containing accessories.
❑ Carefully remove the device from the box (the device not should be lifted or carried by the measuring head).
❑ Removing shipping braces:
  – Loosen device lock knob (**4**, Fig. 2).
  – Basic setup: Turn joystick clockwise (one turn) to move the device upward and pull out the red plate underneath the base axis (patient side).
  – Remove red pads from the wheel housing of the device base.

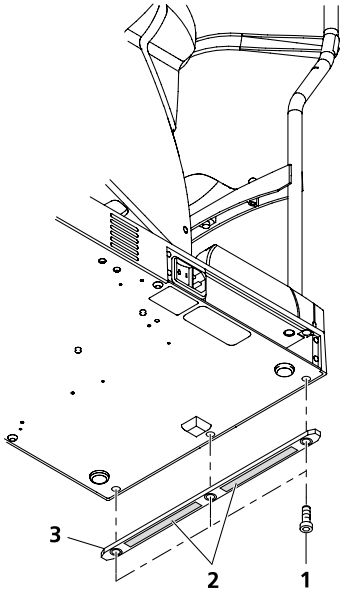


Fig. 7 Mounting holding bracket

Secure device with holding bracket
The IOLMaster can be permanently secured with the aid of a holding bracket (**3**, Fig. 7). Holding brackets with two different widths are available:
  – 7 mm holding bracket for securing to the instrument table
  – 5.5 mm holding bracket for securing to the keyboard support

Caution
The two holding brackets are mounted in the same way. Make sure you use the correct holding bracket.
Do not lift or carry the device by the measuring head!

- Tilt the IOLMaster to one side so that it rests on the patient head support.
- Remove the three hexagon socket (Allen) screws (SW3) (**1**, Fig. 7). The screws may be very difficult to loosen.

Caution
Do not remove any other screws on the base plate! Damage may otherwise be caused to the device.

- Attach the holding bracket with adhesive strips (**2**, Fig. 7) facing outwards.
- Secure the holding bracket with the three hexagon socket screws. Do not yet remove the protective film from the adhesive strips.
- Set the device upright and place it in the desired position.
- Now lift/tilt the device slightly and remove the protective film (**2**, Fig. 7).
- Bring the device carefully into the proposed position. The adhesive strips will hold immediately. The device can no longer be shifted once it has been brought into position!

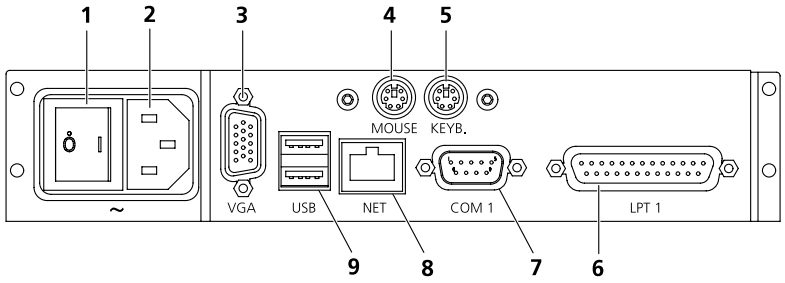
Electrical connection

- Connect mouse and keyboard.
- Optional: Plug in and secure monitor (VGA) and interconnecting cable (NET/COM 1)!
- Connect power cable.
- Install printer as described in Fig. 8.

Caution

Use only printers recommended by Carl Zeiss Meditec! Only one printer may be installed. De-install all surplus printer drivers using menu **Setup** – **Printer**.

Prior to using older printers, please consult Carl Zeiss Meditec whether the printer is approved for use with the IOLMaster.



1	Power switch	**6**	Printer port (LPT1)*
2	Power supply plug (~)	**7**	External PC port (COM 1)*
3	Monitor port (VGA)*	**8**	Network connector (NET)*
4	Mouse port (MOUSE)	**9**	USB interface (USB)*
5	Keyboard port (KEYB)		

Fig. 9 Connection panel

Warning

* If connecting external devices, e.g. an external PC, to the connectors or an external monitor to the VGA connector, the operator must ensure to meet the safety requirements as per DIN EN 60601-1-1 (medical electrical systems)!

A network isolator can be ordered from Carl Zeiss for connection to an external network (NET).

The IOLMaster may only be connected to private networks which are protected from public networks (Internet) by firewalls conforming to the latest technical standards!

When the device is turned on at the power switch, it will run through an internal test. Once this has been completed successfully, the device may be operated. Certain operating parameters are factory set and may be changed in the **Setup** menu (see page 32).

Install printer according to manufcturer's user manual. **Do not connect it to the IOLMaster yet!**

↓

Start IOLMaster and wait until **New Patient** is displayed.

↓

Switch on printer and connect it to IOLMaster (USB/LPT 1). The Windows installation routine will be displayed.

↓

Select option "No, not at this time" and confirm with ***NEXT***.

↓

Insert installation CD for printer driver and wait for language selection to appear in selection window.

↓

Select appropriate language and confirm with ***NEXT***.

↓

If a dialog box for the installation of additional printer software is displayed, exit this box without installing another printer.

↓

The windows installation routine will confirm that installation of the selected printer is finished. Exit with ***FINISH***.

Fig. 8 Installing the printer

General notes on control

The operating system of the device's control computer works in the background. For safety reasons, it is not accessible to the user.

Caution
All attempts to manipulate the operating system are strictly prohibited! In particular, deactivation of the Windows firewall is not permitted!

Windows operating conventions apply analogously to the user interface of the IOLMaster software. This relates to working with a mouse/touchpad, the use of icons, working with dialog boxes and menus, confirmation by double-click, etc.

Note
The system does not support all key combinations of Windows. The special Windows keys that exist on some keyboards are ineffective.

The software uses only a few forced processes. The user may switch freely between the individual modes. For rational working the user is urgently advised to observe the sequence of measurements described from page 38 onwards.

In rare cases, Windows error messages may appear on the LC display. This might be the case, for instance, if the program run is affected (mostly by external disturbances).

Multiple safety mechanisms in the instrument's hardware and software ensure that there is no risk of injury.

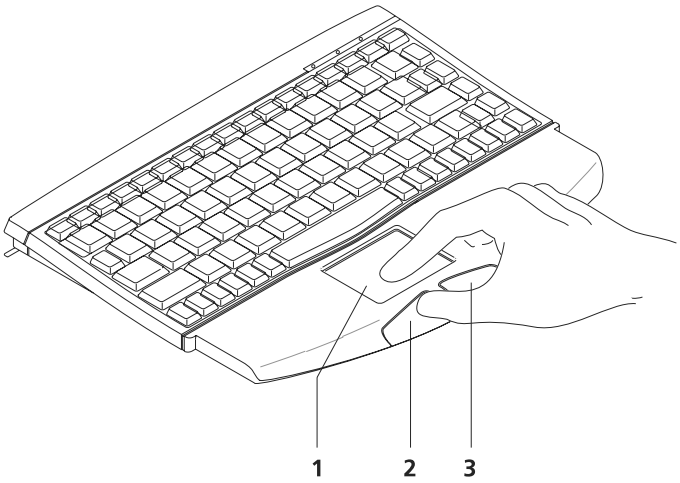
Caution
If warning messages appear frequently, the device should be taken out of service and labelled as such. Then call Carl Zeiss Service.
The device does not support the submission of automatically generated problem reports to Microsoft!

The device may be operated by:

- ❏ using the icons (by cursor, touchpad),
- ❏ keyboard or
- ❏ menus.

Measurements are initiated by pressing the button on the joystick.

Operation by touchpad and keyboard



1 Touchpad
2 Left button
3 Right button

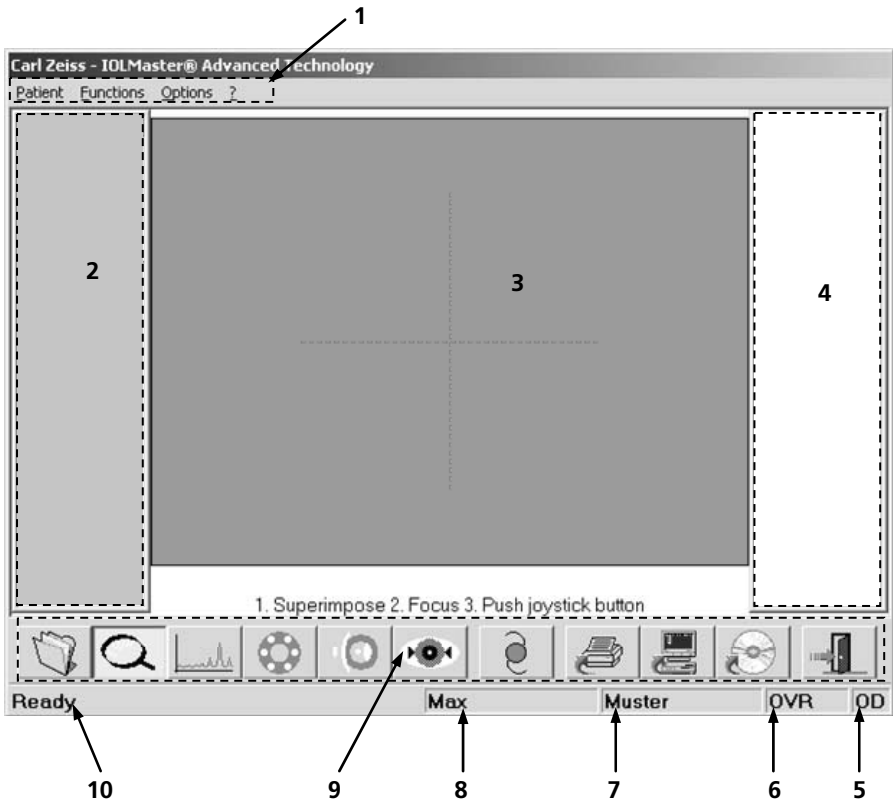
Fig. 10 Touchpad control

- ❏ Move the cursor by touching the touchpad with your finger and moving it as desired.
- ❏ Single and double clicks are possible by tapping a finger on the touchpad or pressing the left button.
- ❏ To drag the cursor, hold the left mouse button depressed while moving the finger across the touchpad.
- ❏ The right button is only functional for:
  - resetting the zoom function (page 77)
  - continuous positioning of the measuring cursor while dragging (see page 79)

Single click	Selection of menu, textbox or entry. Operation of Windows buttons or icons
Double click	OK, confirmation of actions.

In addition to program control via touchpad you may also activate certain menus by pressing individual keys or key combinations (see *Menu overview* on page 26 and *Overview of buttons and shortcut keys* on page 23 ff.).

Screen layout



1 Menu bar
2 Display field for measurements of right eye
3 Display field for video images
4 Display field for measurements of left eye
5 Eye
6 Mode (additionally in ALM mode: number of measurements)
7 Last Name
8 First name
9 Icons
10 System messages/progress bar

Fig. 11 Screen layout

Overview of buttons and shortcut keys

Icon	Key	Function	Explanations
	**<N>**	Activates patient data entry screen.	For new patients, input of patient data is essential.
	**<O>**	Activates overview mode and light spots.	Functions in all modes and for every measurement
	**<A>**	Activates axial length mode.	
	**<K>**	Activates keratometer (corneal curvature) mode.	
	**<D>**	Activates anterior chamber depth mode.	
	**<W>**	Activates WTW determination (optional)	WTW = white-to-white
	**<I>**	Activates IOL calculation.	Calculation already possible after measurement of one eye.
	**<P>**	Prints results obtained hitherto	
	**<S>**	Sends data.	Requirement: A suitable computer must be connected to the serial interface. *
	**<X>**	Transfers data to CD-RW or USB flash drive.	Requirement: CD-RW has been inserted into the drive or USB flash drive is connected to USB port.
	**<E>**	Exits IOLMaster software and Windows and shuts down the device.	Functions in all modes and for every measurement In case of damage: Pull out power supply plug immediately!

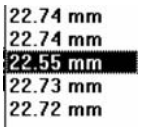
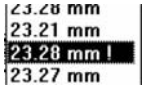
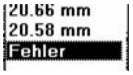


Warning
* If connecting external devices, e.g. an external PC, monitor or an external network, the operator must ensure to meet the safety requirements as per DIN EN 60601-1-1 (medical electrical systems)!

Key functions without icons

Key	Function	Notes
Space bar	Cyclic change of modes: ALM, KER, ACD, WTW	ALM → KER → ACD → WTW …
Joystick button	Program continuation/ activates measurement	In overview mode: change to ALM mode In ALM, KER, ACD and WTW mode
<Del>	Deletes the selected ALM or KER measurement from the list	Only in ALM, KER and WTW mode with acknowledgment
<M>	Briefly inactivates automatic operation	Briefly interrupts adjustment aid automatic function in KER mode
<Ctrl> + <Z>	Restores deleted readings	Effective only in ALM, KER and WTW mode
<Ctrl> + <D>	Effective in ALM mode: Prints the image of the selected graph. Effective in WTW mode: Prints the selected image of the eye.	ALM: One graph only WTW: Right and left eye

Summary of result displays

Display	Meaning	Notes
	3rd axial length measurement (22.55 mm) selected.	Displays measurement curve of this measurement.
	Unreliable value SNR displays YELLOW (SNR = signal-to-noise ratio)	"Borderline SNR" appears above graph. Result should be examined by the user for validity.
	Measuring error SNR display RED	"Error!" appears above axial length graph.
	Result has been manipulated.	* remains displayed even if manipulation has been undone!
 SNR: 6.4	SNR display and SNR (signal-to-noise ratio) beside signal curve	Values for the peak below the measuring cursor.
	Measuring cursor is positioned above signal peak.	

Menu overview

The illustration below provides an overview of available menus and submenus for program operation using the menu commands.

Patient

New
Opens dialog box for entry of new patient; entry compulsory

- **Erase**
  Deletes patient data
- **Rename**
  Renames patient data
- **Export**
  Exports patient data to CD-RW

Send
Sends data via interface

Remark
Edits a comment

Print
Prints measurement table

- **Print current graph**
  Prints the selected graph in ALM mode
- **Print current WTW images**
  Prints the current images in WTW mode

Print preview
Displays print preview

Printer setup
Select printer options

Logout
Logs current user off and opens login window

Exit
Exits application and Windows

Functions

Undo
Undoes last KER/ACD value

Recover
Recovers deleted ALM readings

Overview
Activates overview mode

Axial length measurement
Activates ALM mode

Corneal curvature measurement
Activates KER mode

Anterior chamber depth measurement
Activates ACD measurement

White-to-white determination
Activates WTW determination

IOL Calculation

AL Settings

Accessible in ALM mode only

Phakic

Aphakic

Pseudophakic silicon

Pseudophakic memory

Pseudophakic PMMA

Pseudophakic Acryl

Silicon-filled eye

Silicon-filled eye, aphakic

Silicon filled eye, pseudophakic

Phakic IOL PMMA (0.2 mm)

Primary piggy-back silicon (SLM 2)

Primary piggy-back hydrophobic acrylate

Options

Test eye
Activates/deactivates measurement mode for test eye.

User database
Enters and edits user and IOL data

Setup
Adjusts various settings

- **Date/time**
  Sets system clock
- **Program settings**
  Adjusts program and export settings.User management/User manager
- **Regional settings**
  Windows routine
- **Printer**
  Opens system folder
- **SW option**
  Installs/de-installs software options
- **Update**
  Installs software update

Service
Only for service (password-protected)

?

About IOLMaster
Display and print information on program version

Options menu

Test eye

The calibration of the device can be checked with this function (see Section *Checking the measurement functions* on page 104).

User database

Since the device may be used for the preparation of eye surgery by a number of surgeons at a group practice or clinic, surgeon-specific records may be created. This is performed using the User Manager in the Options menu.

- Click on **User Database** in the Options pull-down menu. The dialog box for entering surgeon-specific data will appear.

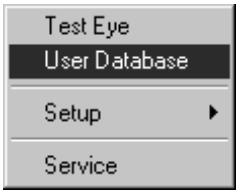


Abb. 12 Options menu

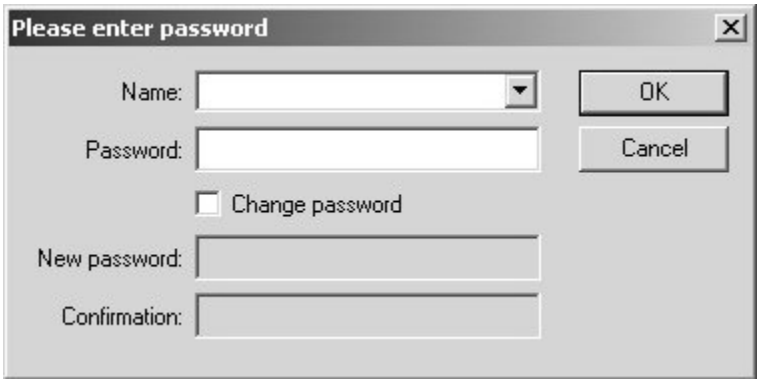


Fig. 13 "Please input password" dialog box

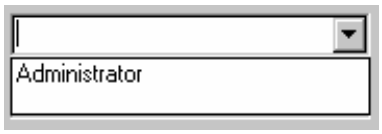
☞ **Note**
When the device is delivered, the User Database only contains the administrator without any password specifications.

Only the administrator is entitled to add or delete users and edit their databases.

Caution:
Individual users may edit their databases only if password protection has been set. If no password protection was set, the databases are accessible to all users!

If **Change password** is checked, the administrator may assign himself a password in this dialog box.

- Type in the password in the **Password** and **Confirmation** text boxes.
- Confirm your entry with ***OK***.



- To create a new user database the administrator must open his or her own database by selecting **Administrator** in the **Name** list box. A dialog box appears, in which new users may be added.

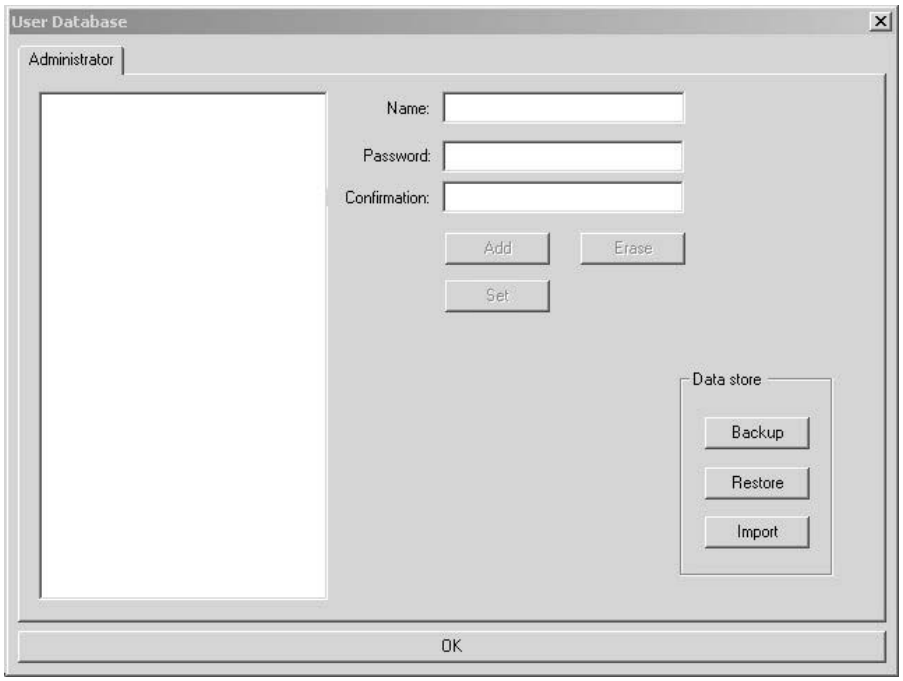


Fig. 14 "User Database - Administrator" dialog box

- Type in the name of the new user.
- If several users share the device it is recommended specifying a password each, which must be repeated in the **Confirmation** text box.
- You can ***ADD*** the new users you have thus entered. In the case of existing users, you can ***SET*** any changes in the name or password.
- If you wish to delete user data from the database, click on the ***ERASE*** button after having selected the name in the left window.
- Click ***OK*** to confirm your user entries. The new user is now registered in the database.
- For the entry of lens data, refer to *Filling the IOL database* (page 55 f).

☞ **Note**
Should a user forget his or her password, the administrator may assign a new password. To do this, the logged-on administrator must highlight the user in the left box and assign a new password with the ***SET*** command button.

Caution
A forgotten administrator password can only be recovered by Carl Zeiss Service!

Data storage

Backup (creating a backup copy)



With the Backup function, you can save to a CD-RW the patient data used for the optimisation of IOL constants together with the IOL data of all surgeons and corresponding lenses used for the calculation.

☞ **Note**
If you wish to export to a CD-RW, you must insert a formatted CD-RW into the drive. The CD-RW must be formatted elsewhere (e.g. office PC) in UDF format. Alternatively, use one of the formatted CD-RWs as supplied. For exporting to an USB flash drive the latter should enable at least a transfer rate to USB-1.1.



Caution:
A compressed and password-protected file is created in the CD-RW. Do not attempt to read or manipulate this file using other programs!

The respective measurement readings are saved together with the patient's personal data, regardless of the set deletion date.

The backup process also includes the tables used for IOL constant optimisation (assignment of surgeon/lens/patient/eye/post-operative data). Additionally, the IOL constants currently used for calculation will be saved for all surgeons.

☞ **Note**
In this way, all critical patient and IOL data can be saved together with the data required for lens optimization. Individual values of axial length, corneal curvature/refractive power, anterior chamber depth, WTW are not saved and may get lost, e.g. in the case of a hard disk fault.

Follow this procedure to create a backup copy:

- In the **User Database** activate **Administrator**.
- Click the ***BACKUP*** command button to initiate the backup process.
- Insert a UDF-formatted CD-RW into the drive.
- Confirm with ***OK***.
- It may be necessary to delete existing data on the CD-RW (conform with ***YES***). Answering with ***NO*** will abort the backup process.
  The data will now be copied to the CD-RW. A progress bar will show the status of the copying process.
- Finally, you will be informed that data backup was successful.

Restore



By using the **Restore** function you can retransfer saved data from a CD-RW to the IOLMaster. Follow this procedure to restore saved data:

- In the **User Database** activate **Administrator**.
- Click ***RESTORE***.
- Insert the CD-RW with the latest backup copy; confirm with ***OK***.
- Confirm with ***YES*** that all surgeon data currently stored on the IOLMaster is to be copied, together with the respective IOL data and patient data available for optimising the IOL constants.
  Database data will now be copied from the CD-RW to the IOLMaster.
  A progress bar will show the status of the copying process.
- Finally, the program will inform you if the restore action was a success.



Caution:
After backed up data has been restored, the user database in the User Manager will reflect the status at the time of backup. All newly registered patients since this time will be irretrievably lost!

Import

The **Import** function permits IOL data (name and respective IOL constants) to be transferred back to the IOLMaster from a database saved to CD-RW or USB flash drive (Version 1.1 or later). Imported data may be assigned to one or several surgeons.
Prior to import, download the available IOL data from the Internet.

Copy the IOL data to a storage medium

☞ **Note**
Download IOL data using a PC connected to the Internet and a CD-(RW-) recorder or USB storage medium.



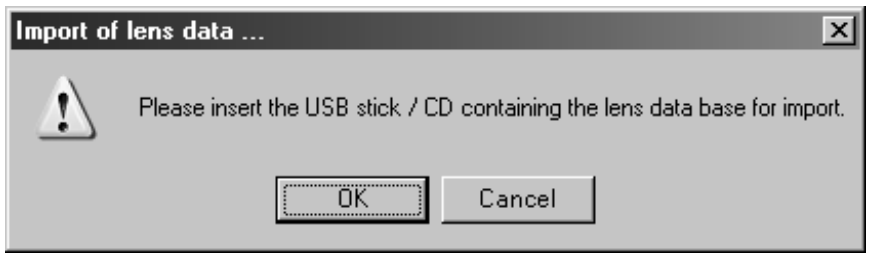
Caution
Do not use a network-connected IOLMaster for the download!

- Log into www.meditec.zeiss.com/iolmaster.
- **IOLMaster** -> **Download**: Select **Optimized IOL constants**.
- Follow the prompts now appearing on the screen.
- Save the file (do not select Open!) on the desired storage medium.
- Do not extract the ZIP file!

Importing IOL data from the storage medium to the IOLMaster

- In the **User Database** activate **Administrator**.
- Click on the ***IMPORT*** button.





- Insert the CD-RW or USB flash drive with the database to be imported and confirm with ***OK***.

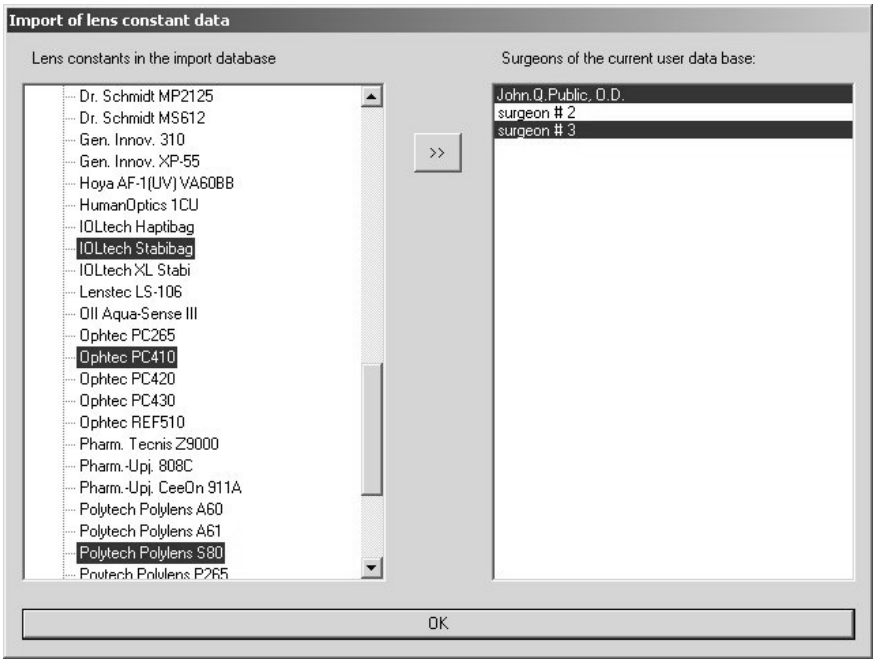


Fig. 15 "Import lens constant data" textbox

- Choose the desired lenses; select several lenses with ***<CTRL>*** + cursor + click (selected lenses appear highlighted in blue).
- Choose the surgeon (one or more) with (<***CTRL***> + cursor + click (selected surgeons appear highlighted in blue); if not already existent, the desired surgeons must be created beforehand.
- Accept with **>>**. A progress bar will show the status of the copying process. The selected lens data will be added to the selected surgeons.
- Close the dialog box with ***EXIT***.



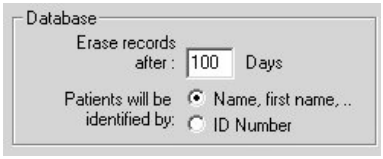
Fig. 16 Setup submenu

Setup

The **Setup** submenu contains the following entries:

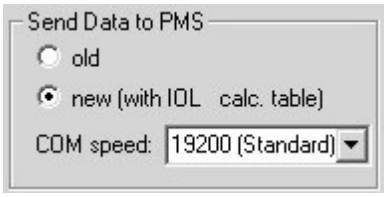
❑ **Date/Time**
Opens the Windows routine for setting the system clock.

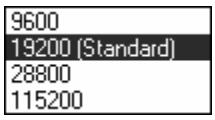
❑ **Program Settings/Program**
- **Language**: IOLMaster dialogs in German, English or other languages (change requires system restart).
- Display of visual acuity: **Decimal** or **Snellen**. Entry of visual acuity in Patient Data dialog box.
- **Database**: Storage time of datasets (5 ... 365 days). All figures between 5 and 365 are possible. 365 days are set at the time of delivery. Data records can be identified or sorted by "Name, first name..." or by "ID Number".





Caution
Please note that when switching from **Name, first name...** mode to **ID Number** all data records without an ID No. will not be listed (entry of an ID is not essential). This also applies analogously to switching from **ID Number** to **Name, first name ...** if a name was not previously entered.





- **Send data**:
  Choose **old**, if the connected office management system only allows import of data of interface software versions 1.01 to 2.02 (patient data, measured values).
  Choose **new** (requires option A plus), if the connected office management system can import all offered data according to interface software version 3.0 and higher.
  COM speed provides a choice of standard transfer rates in kBaud

– **Keratometer display**:
  If you activate the **adjustment aid**, a traffic light will asist the corneal curvature measurement. When the optimum measurement position for the patient has been reached, the traffic light will change from red to yellow to green. If **Automatic** measurement is also activated, as soon as the best possible adjustment to the patient has been reached and the traffic light display turns to green, pressing the knob on the joystick will automatically trigger three successive measurements
  Following a software update, this function must be calibrated prior to first use (see page 103).
  Radius or **Corneal K's** for IOL calculation.
  - Cylinder or **+ Cylinder**
  Refractive Index: Entry of equivalent refractive index for conversion of corneal radii to corneal K's. Enter the refractive index implemented on your keratometer (refer to respective user manual).
– **Printout of the IOL calculation**: Choose whether you wish to have the calculated IOLs of both eyes printed on a single page or only one eye per page. In addition, in this field you may enter the name of the clinic to appear on the printout of the IOL calculation.
  Select emmetropy IOL if desired.

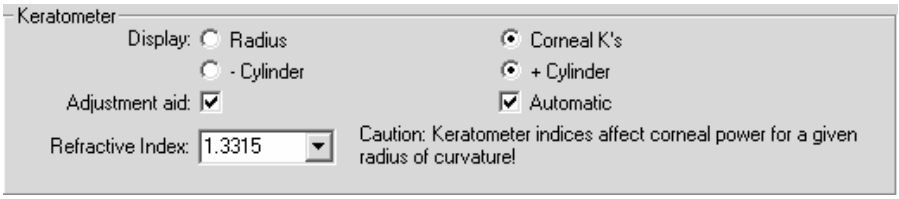


Fig. 17 "Program settings/Program Keratometer" textbox

❑ **Program settings/Export** (requires Option A plus)
  Select export settings. Select the desired form of file printout Identification or Readings and the required printout path. The file name can be freely selected. By convention, the file name may not contain the separators ": / \ ?*"! Data will be saved in (*.csv) text format (separator selectable) and may be read with other applications (e.g. MS Excel):

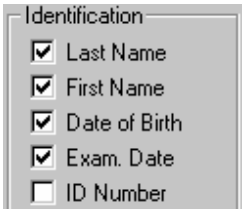


Fig. 18 Data export form "Identification"

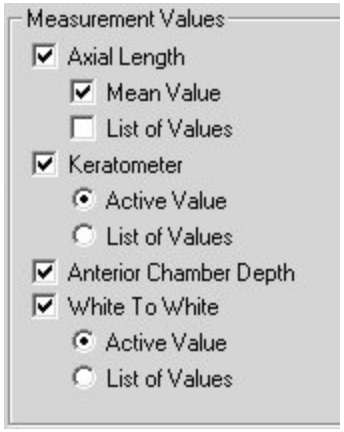


Fig. 19 Data export form "Measurement values"

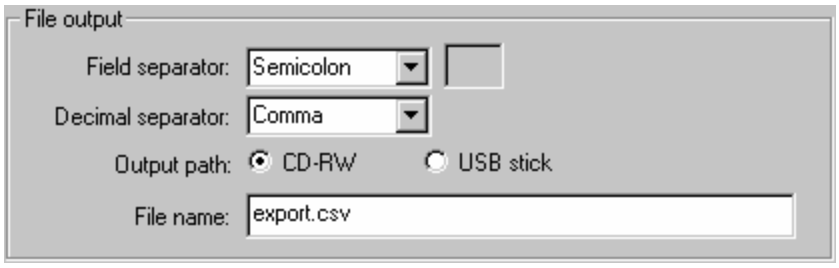


Fig. 20 "Program settings/Export file output" textbox

❑ **Program settings/User management**

– **System login**: IOLMaster and the patient database can be protected by means of a password (acc. to HIPAA). For this purpose, activate the option **User login with password**. A password must contain at least one character.

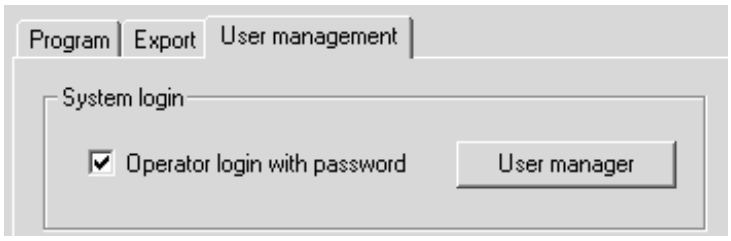


Fig. 21 "Program settings/User adminstration" textbox

Caution:
The option **Operator login with password** and screensaver, together with password protection, should not be activated further users (see below) have been registered and their passwords entered.
If you change the **Admin** password, you are advised to note down the new password, e.g. in the device record book. The user administration system cannot be accessed without the Administrator password!
If the password is lost, a number code will be displayed after three unsuccessful attempts. This number code will enable service personnel to reset the device.

As soon as you have confirmed the new program settings with ***OK***, a login dialog will appear. From now on the IOLMaster can only be used by logging in with password. The default setting is user **Admin** with the password **0000** (4x zero) in the **User Database**. To change the password, select the option **Change password**, enter your user name and old password and confirm with ***OK***.

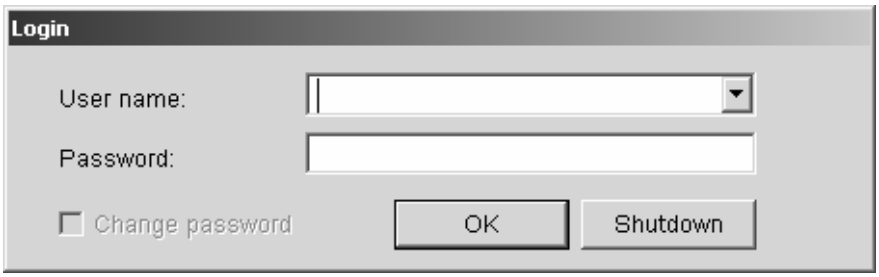


Fig. 22 "Login" dialog box

In addition, a screensaver with a freely adjustable interval can be activated. The screensaver appears if the IOLMaster has been inactive for longer than the set interval. This prevents unauthorised access to protected patient data.
The **Password protection** option offers added protection. If this is activated, you will only be able to work with the IOLMaster and its database after logging on again with the password.

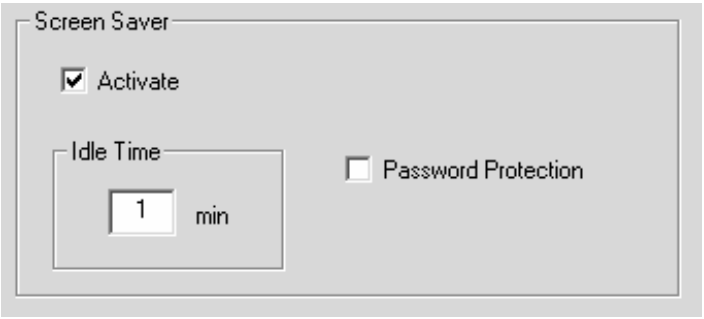


Fig. 23 "Program settings/User adminstration Screensaver" textbox

– **User Manager**: Click on the ***USER MANAGER*** button. The dialog box on the left-hand side of the User Management in the User Manager permits further users to be registered (with the ***New*** button), their password to be specified (**Password**) or users to be deleted (***Delete***).

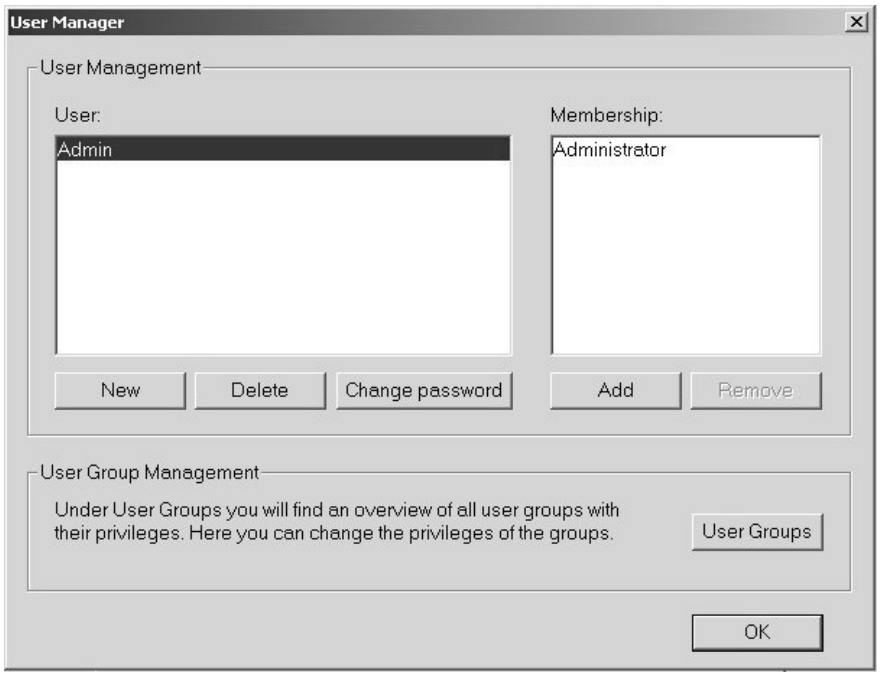


Fig. 24 "Program settings/User administration User Manager" textbox

Each user may be a member of one or more user groups. For this purpose, highlight the respective user. The user groups to which this user belongs are shown in the right-hand window **Membership**.

The user can be assigned to one of the following user groups by clicking on ***ADD***:

- The **Administrator** has unrestricted access rights to **User Management**, the **User Database** (see page 27) and the **Setup** menu.
- The **Surgeon** only has an access right to the respective tab in the **User Database**. This tab is created automatically when the user account is established in the **User Manager**.
- The **Assistant** has no right of access to the **User Database**.

All user groups may enter/rename patient data and perform measurements / calculate IOLs.

Users who are not members of any of the above user groups may work on the IOLMaster in the usual way, but they may not change any of the system settings.

To remove a user from a user group, highlight the name and click on ***REMOVE***.

Note
The rights of the **Surgeon** and **Assistant** user groups in the **User Group Administration** may be extended to include access to the IOLMaster **Setup** menu and the deletion of patient data.

❑ **Regional settings**
Opens the Windows routine for regional settings.

❑ **Printer**
Opens the Windows printer folder This function is only needed for:
- showing the printer queue
- displaying the properties of the installed printer. Here you will find advice on operating and maintaining the printer
- removing a printer that is no longer required (see also page 19).

❑ **SW option**
Installing or de-installing a software version.

❑ **Update**
To install a new software version from a CD:
- Insert an update CD into the drive.
- Click on **Update** to start the software update installation routine.
- Follow the instructions on the screen up to the restart prompt (see Section *Update Installation*, page 102).
- Remove update CD from the drive. If the IOLMaster reappears in **New Patient** mode after restarting, the installation of the software update has been completed.

❑ **Service**
For servicing purposes and password-protected.

Caution:
Unauthorised persons may under no circumstances use the service password. The safety warranty for the medical device will otherwise become invalid!



Preparing for measurements

Switching the device on

- Turn the device on at the power switch (**1**, Fig. 9). The device will start automatically and perform a self-test, after which the Patient Manager screen will appear (Fig. 25).
- After switching on the device will prompt a daily calibration check prior to patient measurements.
- After confirming with ***OK*** check the measurement functions as described on page 104.

Caution:
Axial length [ALM], corneal curvature [KER], anterior chamber depth [ACD] and white-to-white [WTW] should never be measured through contact lenses as this produces incorrect results.

Patient Manager (New Patient)

The Patient Manager manages all existing patient data and the admission of new patients (see Fig. 25; for working with existing patients see page 70).

To admit a new patient, proceed as follows:

The following special characters are permitted for entering patient data:

Minus	-
Dot	.
Apostrophe	'
Underline	_

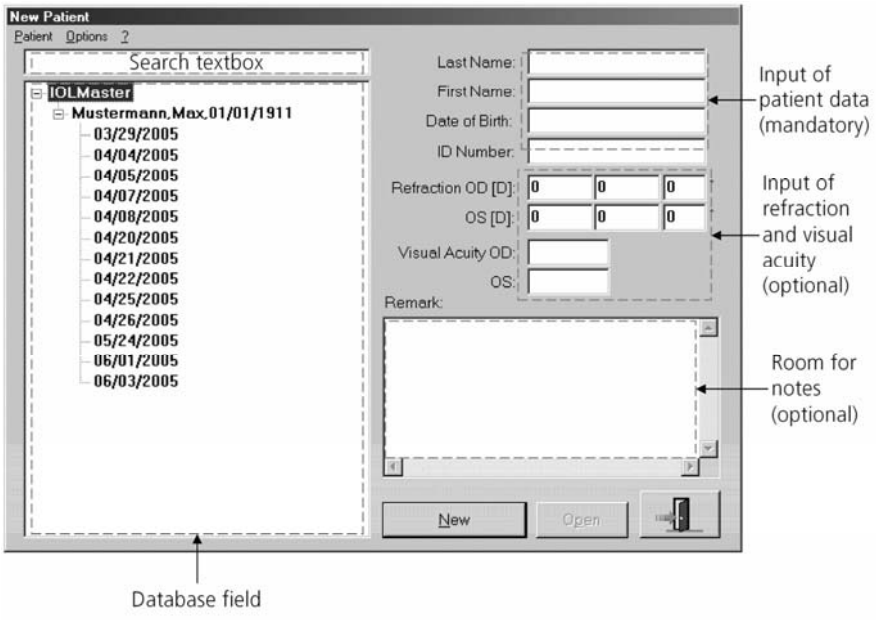


Fig. 25 "New Patient" dialog box

The personal data of patients not yet listed in the database (New Patient) must be entered via the keyboard; no special characters other than "-", ".", "'" and "_" are permissible.

To move the text cursor to the next dialog box press the ***TAB*** or ***ENTER*** key or click the mouse.

☞ **Note**
Depending on the program setting (see page 32), the entry of either the last and first name (case-sensitive) and date of birth or an ID No. is mandatory.
The date of birth will be accepted depending on the Windows setting; the year may also be entered as a four-digit number (yyyy) – mandatory for patients over a hundred years old!

☞ **Note**
It is recommended that the patient's refraction data, if known, be entered in the respective boxes. Visual acuity data can only be entered in the data format set in Program Settings (see page 32).

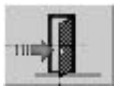
Up to 255 characters may be entered in the **Remarks** field (comments, diagnoses, etc.).

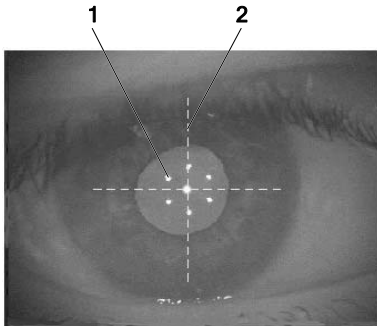
☞ **Note**
Refer to page 70 for working with the database field.
In **Program Settings** you can set the number of days after which a data record is automatically deleted (5 to 365 days).

- To close, after entering the date of birth click on the ***NEW*** button or press the ***ENTER*** key.
  This will automatically activate the **Overview** [OVW] mode. The fixation light and light spots will be switched on. The patient will see a yellow fixation light in the centre and 6 light spots (reflex points in the patient's pupil) will appear in the video image.
- Press the ***NEW PATIENT*** button to open the **New Patient** dialog box in the measurement mode.



- Press the ***EXIT*** icon in Patient Manager to quit the program and Windows.





1 Circle of light spots for focusing
2 Cross hairs

Fig. 26 Video image with correctly set device

Adjusting the device to the patient

The two red ring marks (**3**, Fig. 2) on the side rails of the headrest are for rough vertical adjustment of the chin rest, (**3**, Fig. 3). The patient's eyes should be level with these marks.

In Overview mode, align the device to the patient's eye using the joystick (**1**, Fig. 2). Turn the control knob for vertical adjustment. Tell the patient to look steadily at the fixation point in the centre.

Adjust the device-to-patient distance until the 6 light spots (**1**, Fig. 26) appear focused. If possible, the 6 light spots should be centred on the cross hairs and the edge of the pupil/iris structure should appear in focus.

The position of the device in relation to the patient's eye thus found serves as a starting point for fine adjustments to be made in the respective measurement mode.

Axial length measurement [ALM] with Advanced Technology

The IOLMaster with Advanced Technology features superior signal processing in axial length measurement mode compared to the IOLMaster without this technology. In many cases this enables an overall evaluation of individual axial length measurements (composite signal), producing an axial length result without the need for manual evaluation as described on page 75. In some cases the axial length can even be determined where this would not have been possible from individual readings.
The IOLMaster displays the single signal of the axial length measurement in **red** and it is marked with an **S** on the ordinate. The SNR (signal-noise ratio) is shown on the x-axis.
In contrast, the composite signal is shown in **blue** and marked with a **C** on the ordinate. The increased SNR of the composite signal is likewise shown on the x-axis.

The SNR ranges

- "Measuring error" = red
- "Uncertain value" / "Borderline value" = yellow
- Value with good SNR = green

are signalised by a traffic light.



Measuring error | Uncertain value | Value with good SNR

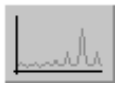
Axial lengths are measured with the IOLMaster with Advanced Technology in the customary manner, or as described on page 43.

Take at least five individual measurements. The axial length measurement signal for the first four measurements is displayed as usual immediately after the measurement. From the fifth individual measurement, the composite signal is calculated in the background. After each individual measurement the axial length signal (red) is thus first of all briefly displayed for about 1 second. This is followed by the display of the composite signal (blue).
In addition, insofar as it could be determined, the axial length measurement of the composite signal is displayed below the horizontal bar in the list of measurements.

If no axial length reading could be determined after the first five individual measurements, additional measurements should be taken. With stronger lens opacities, it may be advisable to defocus the device. You may choose a reflection as large as the circle on the display. Also try measurements by height variation (turning the joystick) of the refocused reflection at the lower and/or upper edge of the circle on the display. Ensure that the device permits no more than 20 measurements per eye and day.

The overall axial length measurement is post-run edited as described on page 78 onwards.

Axial length measurement [ALM]

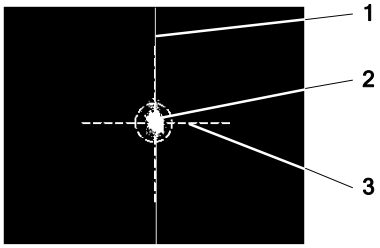


Activate the ALM measurement mode by:

- clicking on the ***ALM*** icon
- pressing key ***A***, or
- pressing the button on the joystick in Overview mode [OVM].

Switching to ALM mode will automatically change the magnification ratio: a smaller section of the eye becomes visible with the reflection of the alignment light and a vertical line (**1**, Fig. 27).

- The patient should look at the red fixation point in the centre. A crosshair (**3**, Fig. 27) with a circle in the middle will appear on the display.
- Fine-align the device so that the reflection of the alignment light (**2**, Fig. 27) appears within the circle.



1 Vertical line
2 Reflection of alignment light
3 Cross hairs

Fig. 27 View prior to axial length measurement

Warning
The patient should be asked if he or she sees the fixation point. If the patient fails to fixate properly, the visual axis will not be correctly recognised, which may result in measuring errors.
In the case of poor visual acuity/high ametropia (> 4 D) it is advisable to measure through the spectacles. If the procedure is followed correctly, no measuring errors will be produced. Measurements should not be taken while a patient is wearing contact lenses, as this will result in measuring errors.

- Trigger the measurement by pressing the knob on the joystick.

The corresponding display field next to the video image will show the measured axial length. The video image will be overlaid with a red graph similar to those in ultrasonic measuring instruments. The signal-noise ration [SNR] will be displayed simultaneously as a value. This value is a gauge of the quality of measurement. Measurements with an SNR between 1.6 and 1.9 appear with an exclamation mark (!) after the reading and the message "*Borderline value!*" will appear. (evaluation of SNR see *Post-run editing of axial length measurements*, page 78 ff.).

Readings that deviate from the internally calculated mean value by more than 50 µm are shown in red and marked "multiple peaks".

Note
"*Borderline value!*"*(Uncertain value)* does not necessarily mean that the reading is incorrect and must be rejected. It rather means that all axial length measurements for the eye should be checked for plausibility and consistency, e.g. according to the usual ultrasonic biometry criteria. If the "uncertain" values are determined to concur with the other readings, the readings marked "*Borderline value!*" should also be accepted as valid axial lengths.

☞ **Note**
The IOLMaster requires five measurements to be taken! The message **Measure again** will thus appear. Only then will the composite signal be calculated and displayed as a blue measurement curve following the red individual measuring signal. If an axial length measurement can be determined from this composite signal, it will be transferred to the IOL calculation and an evaluation will be performed. Only the number of measurements is crucial here. To obtain consistent results we recommend checking the individual axial length measurements and carrying out further measurements if necessary.

With stronger lens opacities, it may be advisable to defocus the device. You may choose a reflection (**2**, Fig. 27) as large as the circle on the display. If measurements are even now impossible, the device can be refocused and the reflection shifted to the bottom and/or top margin of the circle on the display by varying the vertical adjustment (turning joystick).

☞ **Note**
Defocusing and shifting the reflection within the circle will have **no effect** on the result, because interferometric axial length measurement is completely independent of distance.

- For the next measurement of this eye, press the button in the joystick.

⚠ **Warning**
Up to 20 such measurements per eye may be taken on a single day.
Avoid measurements of eyes with retinal detachment. In such cases, measuring errors cannot be precluded.
As a rule, the axial length should be viewed together with the values for corneal refraction and overall refraction, and checked for plausibility. It is likewise helpful to compare the right and left eyes.

The composite signal is calculated after the fifth measurement. Initially, the individual signals are displayed in red. After a delay of about 1 second the composite signal is then displayed in blue. In addition, the axial length reading determined from this composite signal will appear. The composite signal will be re-calculated after each further individual measurement, and an axial length calculated therefrom. Should a reading deviate from another by more than 0.05 mm, it will be displayed in red and the message **Multiple peaks** will appear. This indicates that the individual measurements should be scrutinised and the composite signal may need to be post-run edited (see *Post-run editing of axial length measurements*, page 78 ff.).

Until an axial length can be determined from the composite signal, the word **Evaluation!** will be displayed below the horizontal line in the list of measurements. If necessary, the potential individual measurement errors must be deleted or the composite signal post-run edited, as the readings obtained will not otherwise be accepted for the IOL calculation and database for optimisation of the lens constants. Until the fourth individual measurement has been taken, the last reading will be highlighted in blue. From the fifth individual measurement onwards, the composite signal is highlighted in blue. The blue highlighting can be moved through the table of individual readings with the aid of the cursor buttons ↑↓. In this way the signal curves of the individual measurements can be displayed. Deleted individual measurements can be restored with the shortcut ***<CTRL>* + *<Z>***. The composite signal can be displayed by clicking on the composite reading.

Error in the display field denotes readings with an SNR smaller than 1.6.

The following plausibility tests are performed with the axial length measurement (AL) from the composite signal:

AL < 22mm (indication of short ocular axis, use corresponding biometric formula)
AL > 25mm (indication of long ocular axis, use corresponding biometric formula)

When both eyes have been measured, the difference in axial lengths between right and left is also checked. If the latter exceeds 0.3 mm, a message appears to check the readings once again.

If this warning appears, be sure to verify that no pathological changes have occurred in the eye. If necessary, the measurements must be repeated (provided the maximum of 20 measurements per eye and day has not already been reached). Only confirm the warning with **OK** if you are certain that the readings are plausible. Otherwise, determine what has caused the implausible readings. A reference to the displayed plausibility test message will be transferred to the comments box.

The number of measurements of the respective eye taken on this particular day is displayed in the **Mode** field of the status bar next to "ALM". If the count reaches 20 no further measurements of this eye can be taken on this day. The counter cannot be reset. Deleted readings (see above) do not affect the measurement counter!

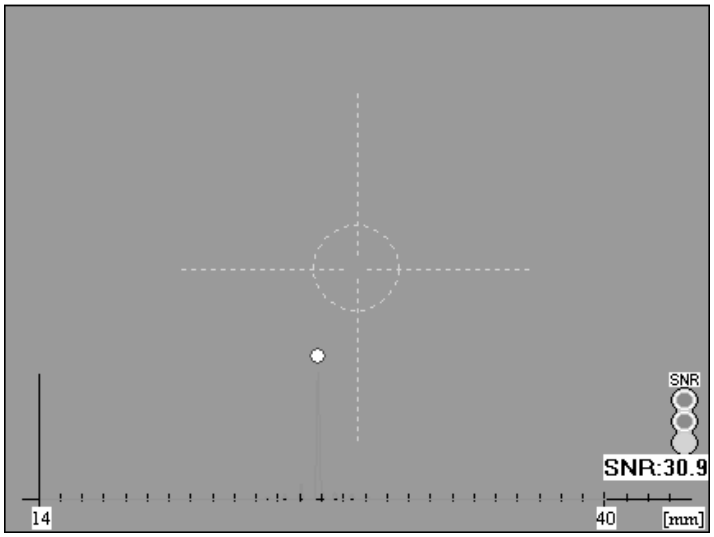


Fig. 28 Video image after axial length measurement

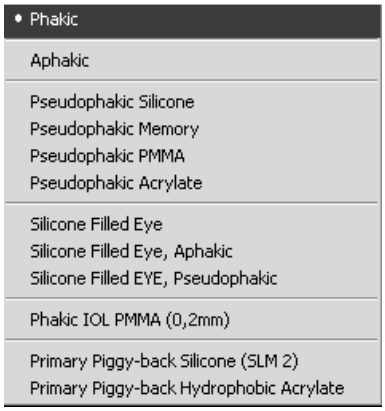


Fig. 29 AL settings

Sample calculation for a phakic implant (Acrysof) with a centre thickness of 0.2 mm:
Measured value: 23.51 mm
Compensation value: -0.03 mm
Correct axial length:
23.51 + (-0.03) = 23.48 mm

ALM measurement of non-phakic eyes
To measure non-phakic eyes, select the corresponding mode from the **AL settings** menu. This special AL mode is displayed in the video image field and will be active until you reset it via the menu. The device will also be reset to **phakic** mode if you change to the patient's other eye or a new patient.

If the axis length of eyes with phakic implants not listed in the additional AL settings is to be measured, the following compensation values according to PD Dr Wolfgang Haigis of Würzburg University Clinic, Germany, should be used.

IOL centre thickness / IOL material	0.2 mm	0.5 mm	0.8 mm
Silicon 3 (SLM2)	-0.02 mm	-0.04 mm	-0.07 mm
PMMA	-0.02 mm	-0.06 mm	-0.09 mm
Acrysof	-0.03 mm	-0.08 mm	-0.13 mm

Every implant, e.g. a phakic IOL, influences the measurement of axial length in PCI biometry. If a phakic implant is measured in a normal phakic mode, the result will be slightly elevated. The reading must be corrected, depending on the material used and the centre thickness.

Warning
Two peaks may appear when measuring pseudophakic eyes and with certain intraocular lenses. The first peak is a side maximum of the IOL, while the second peak is produced by the retina. In this case, manual correction is necessary (see *Measuring errors with pseudophakic eyes* on page 76). It is expedient to measure at a number of different points.

Warning
Use the **psph** (pseudophakic) button to calculate secondary piggy-back IOLs. For this purpose, the ACD should be measured by a method other than the IOLMaster and the readings thus obtained entered into the appropriate boxes.

Measurement of corneal curvature [KER]

Keratometer measurement

Activate the KER measurement mode by:



- clicking on the ***KER*** icon
- pressing the ***<K>*** key
- pressing the ***<SPACE BAR>*** in ALM mode [ALM]
- Tell the patient to focus on the yellow light!
- Align the device so that the 6 peripheral measuring points are symmetrical to the circular crosshair and appear optimally focused. The central point is usually not focused and is not evaluated for keratometer measurement! The IOLMaster with Advanced Technology indicates the optimum measurement setting by means of a green traffic light.

Note
Ensure that all 6 peripheral points are visible and located in the field between the two auxiliary circles on the display. It is recommended that the patient blink his/her eye shortly before the measurement to produce a continuous tear film. This will improve the reflectivity of the cornea. The measuring points should be circular or ellipsoid. If the measuring points are irregular (i. e. corneal scar) measurement is not possible. Precise measurements are possible only if the 6 peripheral measuring points appear optimally focused on the display.

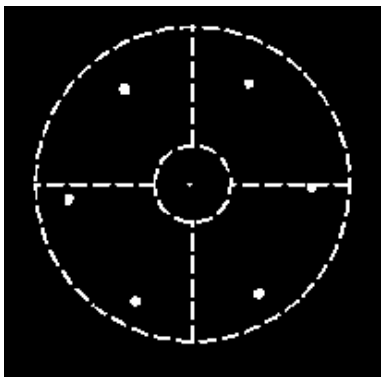


Fig. 30 Setting for keratometer measurement

- Trigger the measurement by pressing the knob on the joystick.

Depending on the setting under **Program settings/Program** (see page 33), a traffic light will assist in finding the optimum measurement setting. When the optimum measurement position has been reached, the traffic light will change from red to yellow to green. Once the optimum measurement setting (green traffic light) has been reached and remains constant for all three measurements, pressing the knob on the joystick in **Automatic** mode (**Automatic activated**) will trigger three consecutive measurements. The automatic measurement procedure will be interrupted if the optimum measurement setting (green light) wavers and is resumed when the optimum setting is reinstated.

Five internal individual measurements are taken for a single keratometer measurement within 0.5 seconds. Following this, the radii or corneal K's (depending on program settings) of the two main sections will be displayed, together with the respective axial orientation and the astigmatic difference. In the case of a spherical cornea, only the radius or a corneal K will be displayed, but no axial orientation or astigmatic difference. A blue progress bar in the status bar will indicate the progress of computation.

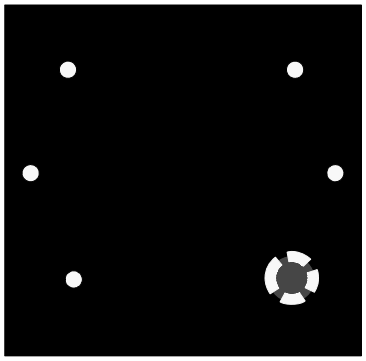


Fig. 31 Measurement point not identified

The size and shape of measurement points will be verified by the software. If a measurement point is not correctly identified, a blue flashing dot will appear. In the printout this will be marked by an **x**. These readings should not be used and a new measurement should be taken as a precaution.
Keratometer measurements may be repeated as often as desired; however, only the last three measurements will be displayed.

☞ **Note**
The IOLMaster requires three measurements to be taken! The message **Measure again** will thus appear. Only then will a mean value be passed on to the IOL calculation and an evaluation enabled. Only the number of measurements is crucial here.

☞ **Note**
In some cases (keratoconus, keratoglobus, corneal lesions, etc.) it may not be possible to reach the green traffic light. In such cases the traffic light display can be briefly deactivated, enabling a measurement to be taken even when the light is on yellow or red. To do this, press the ***<M>*** key. The **Automatic** display will disappear. However, now pay attention to the correct setting, as described above. Press the ***<M>*** key once again to reactivate automatic. Automatic will always be switched back on for a new patient.

To delete one of the three displayed readings, highlight it and press ***<DEL>*** or ***<CTRL>*** + ***<Z>***. Then confirm with ***YES***.

If the last three readings differ by > 0.5 D (mean value of the spherical equivalent of the last three measurements) or if the tolerance of the mean radius of the last three readings of 0.08 to 0.1 is exceeded (dependent on n), the **Evaluation!** message will appear on the screen.

- In this case, check the tear film of the eye being examined, ask the patient to blink if necessary and repeat the measurements until the results are within the tolerances. The **Evaluation!** message will then disappear.

- Potential measuring errors (inaccurate measurements) must be deleted as necessary, since the readings obtained in the **Evaluation!** state will not be accepted for ACD measurement, IOL calculation and the database for optimization of constants.

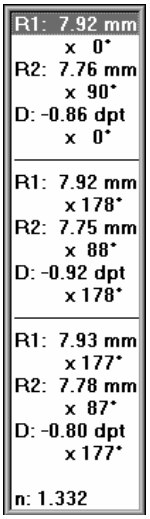


Fig. 32 Three keratometer readings

Warning
To obtain consistent results we recommend checking the individual keratometer measurements and carrying out further measurements if necessary.

The following plausibility tests will be made with the keratometer reading:

R > 8.4 mm ⇨
Indicates possibility of a very flat corneal curvature, keratoglobus

R < 7.2 mm ⇨
Indicates a very steep corneal curvature

R < 7.0 mm ⇨
Indicates possible keratoconus

|R1 - R2| > 0.5 mm ⇨
Indicates high astigmatism

When both eyes have been measured, the difference in the keratometer readings between the right and left eye will be checked. If this exceeds 0.2 mm or 1 D, you will be prompted to check the readings once again.

If this warning appears, be sure to verify that no pathological changes have occurred in the eye. It may be necessary to repeat the measurements. Only confirm the warning with **OK** if you are certain that the readings are plausible. Otherwise, determine what has caused the implausible readings. A reference to the displayed plausibility test message will be transferred to the comments box.

Measurement of anterior chamber depth [ACD]

Warning
The anterior chamber depth may only be measured on phakic eyes! ACD measurements of pseudophakic eyes result in measuring errors and/or incorrect readings. The readings for pseudophakic eyes do not reflect the anterior chamber depth.

Note
The keratometer measurement must be performed before anterior chamber depth measurement!

Activate the ACD mode by:



- clicking on the ***ACD*** icon
- pressing the ***<V>*** key or
- pressing the <***SPACE BAR***> in KER mode [KER]

The lateral slit illumination will automatically be turned on. This illumination subjectively appears to be very bright to patients. Nevertheless, the patient should continue to concentrate on the yellow fixation light.

- Fine adjust the device, so that:
  - the fixation point is displayed in optimum focus in the rectangle on the screen (only the fixation point should be within the rectangle, not the other image details)
  - reflections do not cause interference to the image of the cornea, otherwise the reading will be incorrect
  - the anterior crystalline lens is optimally visible!

As a rule, the image of the fixation point will lie between the images of the cornea and the crystalline lens. It should be close to (but not within) the optical section of the crystalline lens! For system reasons, the corneal image will be out of focus.

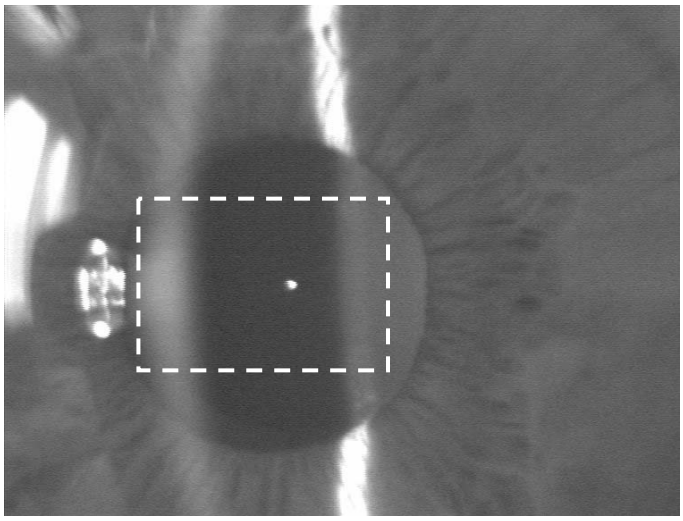


Fig. 33 Setting for anterior chamber depth

☞ **Note**
The alignment of the device, particularly in the case of small pupils, requires a certain amount of practice on the part of the operator and cooperativeness on the part of the patient. The alignment procedure is easier on a dilated pupil (see also *Tips for anterior chamber depth measurement*, page 93 ff.).

- Trigger the measurement by pressing the knob on the joystick.

☞ **Note**
Before starting, tell the patient to look steadily at the fixation light – not into the slit projector, as the latter will flicker during the measurement! When an acoustic signal is heard – the slit will again illuminate steadily – the measurement has been completed and the ACD values will be calculated.

Note: Anterior chamber depth on the IOLMaster is interpreted as the distance between the anterior vertex of the cornea and the anterior vertex of the eye lens. Hence, the displayed distance includes the thickness of the cornea. Calculation of the anterior chamber depth requires the input of the corneal radius. If a valid keratometer measurement was performed prior to ACD measurement, the system will automatically use the measured radius for the calculation. If for any reason the IOLMaster was unable to measure the corneal curvature, a window will appear requesting you to type in the radius (if the cornea is astigmatic, the values of both principal meridians).

- Enter a value between 4.0 and 13.0 mm (use decimal point). Continue with ***OK*** or the <***ENTER***> key.
  If you have selected the display **Corneal K's**, please enter a number between 26 and 80 (D). When entering the refractive power, make sure that the same keratometer refractive index is set on the IOLMaster as on the keratometer used for the measurement (see page 32).

A blue status bar will appear in the message bar. Five ACD readings will be listed in the display field next to the video image, together with the calculated mean value.

The anterior chamber depth measurement may be repeated as often as desired.

If additional measurements are taken of anterior chamber depth, the previous readings will be overwritten. To restore the last (just overwritten) readings, press shortcut keys ***<CTR>*** + ***<Z>*** (UNDO function).

☞ **Note**
This UNDO function itself is irrevocable!

Determination of "white-to-white" [WTW] (optional)



Activate the WTW mode by:

- clicking on the ***WTW*** icon, or
- pressing the ***<W>*** key
- pressing the ***<SPACE BAR>*** in ACD mode [ACD]
- The patient should look at the yellow fixation point in the centre.
- Align the device so that the six peripheral light spots are symmetrical to the cross hairs and the iris structures or the edge of the pupil appears optimally focused. The fixation point in the centre of the 6 light dots is usually not in the centre of the pupil or iris, because only in the rarest cases does the visual axis correspond to the optical axis of the eye.



Warning
The patient should be asked if he or she sees the fixation point. If the patient fails to fixate properly, the visual axis will not be correctly recognised, which may result in measuring errors.

- Trigger the measurement by pressing the knob on the joystick.

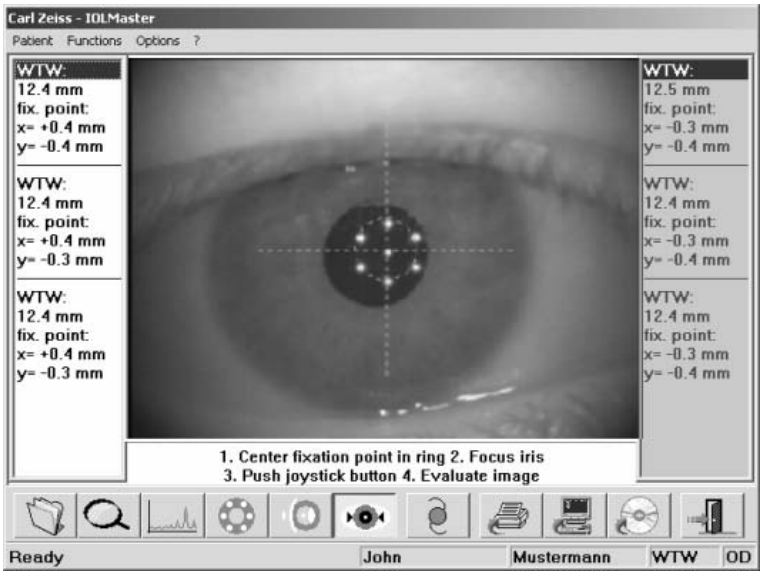


Fig. 34 WTW determination

Each time the joystick knob is pressed, an image of the eye is displayed, in which the detected iris edge is marked. After checking that the iris and fixation point have been correctly recognised, confirm with ***OK***. Only then will the data be valid and available for further processing.

Warning
The validity of the WTW determination depends on this check of correct recognition of the iris edge.
The WTW value is the horizontal diameter of the iris. In addition to the WTW value, the deviation of the visual axis from the centre of the iris (x, y) will also be displayed (Fig. 34).

The values are stated in millimetres with reference to a Cartesian coordinate system, the zero point of which is assumed to be in the established centre of the iris or pupil. If the visual axis is above the iris or pupil centre, the Y value will be positive; if it is below, the value will be negative.
X values to the left of the centre are negative; those to the right are positive.

☞ **Note**
If the software has difficulty detecting the iris or fixation point, this may be due to inadequate room lighting. It is recommended that the front panel and examined eye be shielded from direct or lateral light. The best results will be obtained when the examination room is slightly darkened.

WTW measurement may be repeated as often as desired.

Measuring the other eye

The system automatically registers which eye is being measured (OD or OS). All past readings of this patient are still stored and may be retrieved as necessary.

Measurements of the other eye must be performed analogously to the previous eye.

☞ **Note**
After each change of side, the overview mode [OVW] is automatically activated for coarse alignment.

Printout of results

Once the measurements have been completed, the readings, composite signal and a diagram of iris, pupil and WTW can be printed out.

Caution
Consult the user manual supplied with the printer. Connect the printer as described in *Setting up the device for use* on page 19.

☞ **Note**
The following print formats are supported (upright format only): A4 (210 x 297 mm), Letter (8.5" x 11.0"), B5 (182 x 257 mm).

The printout of the readings may be started from every measurement mode (ALM, KER, ACD, WTW). The printout will include all results obtained so far (also those of the other eye, if already available). It is advisable to start the printout only if all results of both eyes are available.

☞ **Note**
Do not take any further measurements during the printing process.



Press the ***PRINT*** icon or ***<P>*** key to start the printing process

☞ **Note**
In ALM mode the printout of the graph with the blue highlighted reading can be enlarged by pressing ***<CTR>*** + ***<P>***. For enlarging the display of the graph see page 77.
In WTW mode the current reading can be printed out using ***<CTR>*** + ***<P>***.

Generation of IOL options

Once all measurements have been taken (depending on the IOL calculation formula), options can be generated for intraocular lenses to be implanted.

Filling the IOL database

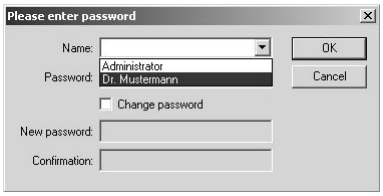


Fig. 35 "Please input password" textbox

Before the system can calculate IOL options, the available lens types must be entered into the database.

- In **Options – User Database** open the **Please enter password** dialog box.
- Select the appropriate name and enter password as necessary. The database window for entering the specific lens data will open (for registering a new user see page 27).

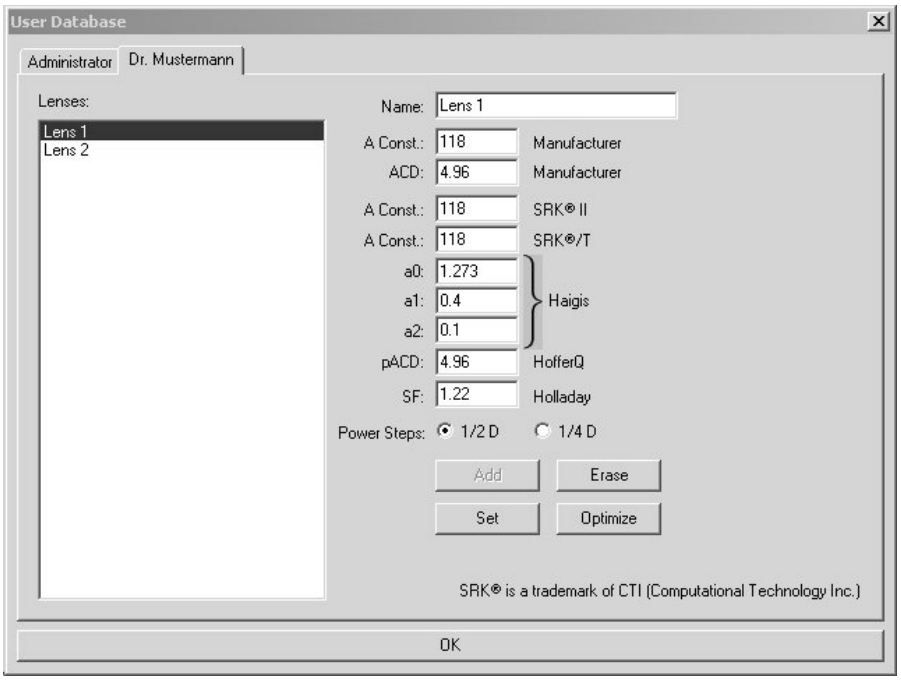


Fig. 36 Database window for the input of lens data

- In the lines **Name**, **A Const. Manufacturer** and **ACD Manufacturer** enter the respective data for the manufacturer, from catalogues or package inserts.

Warning
If the ACD constant is not available, you may click the ***ADD*** button after entering the A constant. All parameters will automatically be calculated from the A constant according to standard formulae. However, the manufacturer's A constants are not optimal for optic biometry and may result in refractive deviations.

- Your IOL constants or personally calculated constants for various calculation formulae optimised for optical biometry must be entered/changed in the **A Const. SRKII**, **A Const. SRK/T**, **a0**, **a1**, **a2**, **pACD** and **SF** boxes.

Note
Only constants optimized for optical biometry should be used for calculating the suggested strength of the intraocular lens to be implanted with the IOL Master, not the manufacturer's IOL constants (see also pages 63 and 82).

- If you use lenses graded in 0.25 D intervals (in future), activate the **Power Steps 0.25 D** radio button.
- To add data to the database, click the ***ADD*** button.
- To delete the data of the lens type selected in the Lens field, click the ***ERASE*** button.
- By clicking the ***SET*** button, existing lens data will be overwritten by edited data.
- To enter the data of the next lens, overwrite the name of the lens. Exit the User Database by clicking on ***OK***.

IOL calculation



Start the calculation by:

- clicking on ***IOL*** or pressing the ***<I>*** button.

The IOL calculation window appears in which the measured values of both eyes are automatically entered. Depending on the choice of refractive power/radii in the **Program Settings** submenu (page 32), the keratometer readings are displayed in either Corneal K values (D) or Radii (mm).

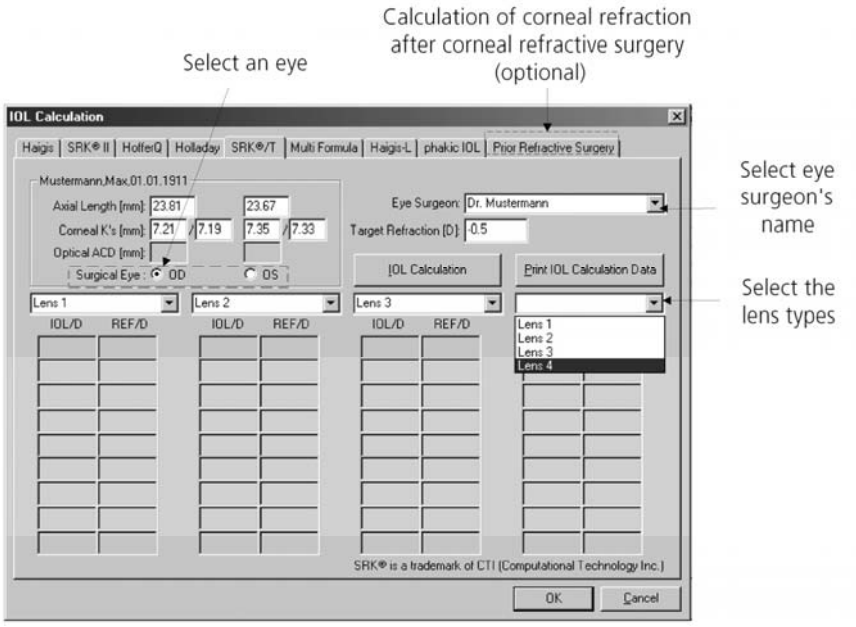


Fig. 37 IOL calculation window "SRK®/T"

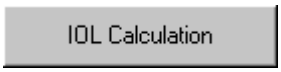
- Click on the appropriate tab to select the desired formula. The IOL Haigis, HofferQ, Holladay, SRK II, and SRK®/T formulae are implemented as standards.
- After refractive corneal surgery the **Haigis-L** or **Prior refractive surgery** tabs may be selected.
- Selected phakal implants may be calculated with the **Phakic IOL** tab.
- Select the eye surgeon's name. This gives the surgeon access to lens types saved to his database.
- The measured values may be edited if desired.

Warning



Edited readings appear with an asterisk (*) in the printout of the lens calculation and the lens calculation is no longer based on the IOLMaster readings!

- Select an eye for which the IOL is to be calculated on the screen.
- Enter the desired target refraction. No entry means 0 D (plano).
- Select suitable lenses from the lens types shown.
- After you have entered the necessary data, click on the ***IOL CALCULATION*** button. This will start IOL calculation of each lens type selected. The calculation will be performed for every measured eye. However, only the data of the selected eye is displayed on the screen.



- To change the display, select the other eye under **Surgical Eye**. The lenses calculated for the other eye will now be displayed.

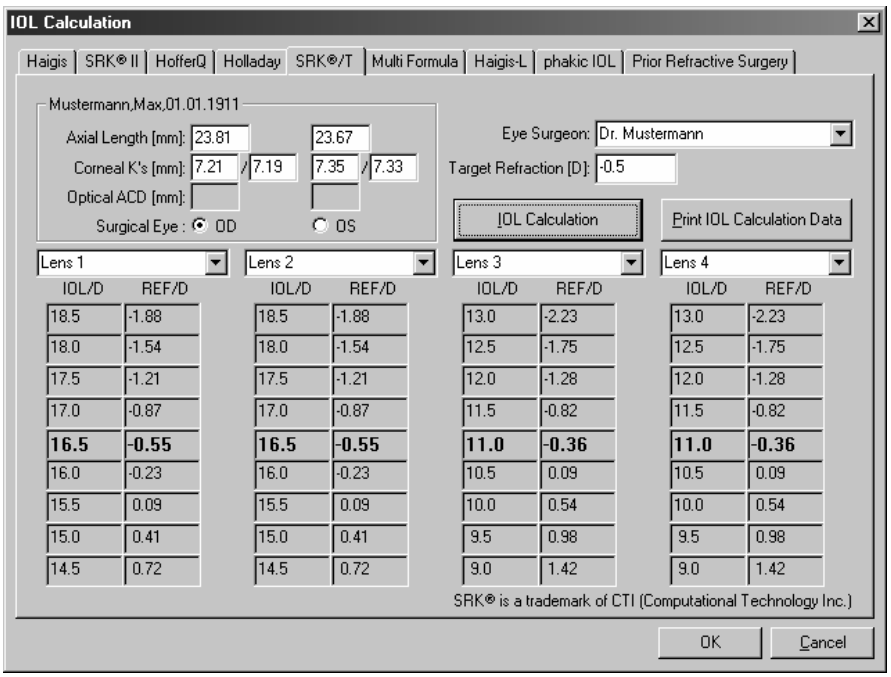


Fig. 38 Calculated IOL data in IOL calculation window "SRK®/T"

In the columns below each specified lens you will find the calculated refractive powers and target refractions for those lenses. The middle line appearing in **bold** type indicates which refraction of the corresponding IOL comes closest to the desired target refraction.



Warning
The IOL calculation is valid only if the biometric measurement was correct, an appropriate IOL calculation formula was selected and the IOL constants were optimized for the specific application.

The data calculated for the IOL to be implanted can be printed out.

- For this purpose, click on the ***PRINT*** button.
  The IOL data of both eyes or of one eye and emmetropic IOL will be printed out either on a single page or on separate pages, depending on the option selected in the **Program Settings** menu (page 32).
- Click on ***OK*** to finish IOL calculation.

IOL calculation after corneal refractive surgery (optional)

Corneal refraction is an important quantative factor in IOL calculation. Presently, it is impossible to exactly measure the corneal refraction that was subjected to corneal refractive surgery (e.g. by RK, PRK, LTK, Lasik or Lasek). For this reason, a different method of determining corneal refraction must be adopted for the IOL calculation. Three methods are available:

- ❑ Refractive history method
- ❑ Contact lens method
- ❑ Haigis L method, should the preLasik or corresponding contact lens values not be available.

Prior to calculating an option for an intraocular lens, the corneal refraction must be determined.

Start the calculation by:

- clicking on ***IOL*** or pressing the **<*I*>** button.
- selecting **Prior refractive surgery**.



Warning
This step is necessary only with corneas pretreated by refractive surgery. With untreated corneas, IOL calculation starts instantly upon selection of the biometric formula (see IOL calculation on page 56).



Refractive history method

The following values must be known for the refractive history method:

- ❑ Preoperative corneal refraction (i.e. before corneal refractive surgery)
- ❑ Preoperative refraction
- ❑ Stable postoperative refraction
- ❑ Corneal vertex distance.

As the change in refraction was achieved by variation of the corneal refraction, the currently effective corneal refraction directly results from the difference between preoperative and postoperative refraction, corrected by the corneal vertex distance (vertex correction). The computational method is described in the technical literature. If the corresponding data of the patient is available, the refractive history method delivers the most accurate results.

For the calculation of the IOL, the corneal K's selected by the examiner with ***APPLY*** will be transferred to the IOL calculation table. The IOL calculation can be started after selection of the biometric formula.

Contact lens method

The contact lens method (contact lens overrefraction) attempts to determine the currently effective corneal refraction on the basis of two refraction measurements, once with and once without a hard "plane" contact lens.

The following parameters are needed:

- ❏ Refraction with contact lens,
- ❏ Refraction without contact lens,
- ❏ Refractive power of the (plane or almost plane) hard contact lens – refractive power of contact lens back surface and
- ❏ Corneal vertex distance.

In the ideal case, the refractive power of the contact lens back surface is equal to the unknown corneal refraction. For this purpose, several hard plane contact lenses with refractions of the back surface between 30 and 45 D should be available. For the calculation of the corneal refraction, enter the appropriate patient data into the display mask. The values will now be calculated.

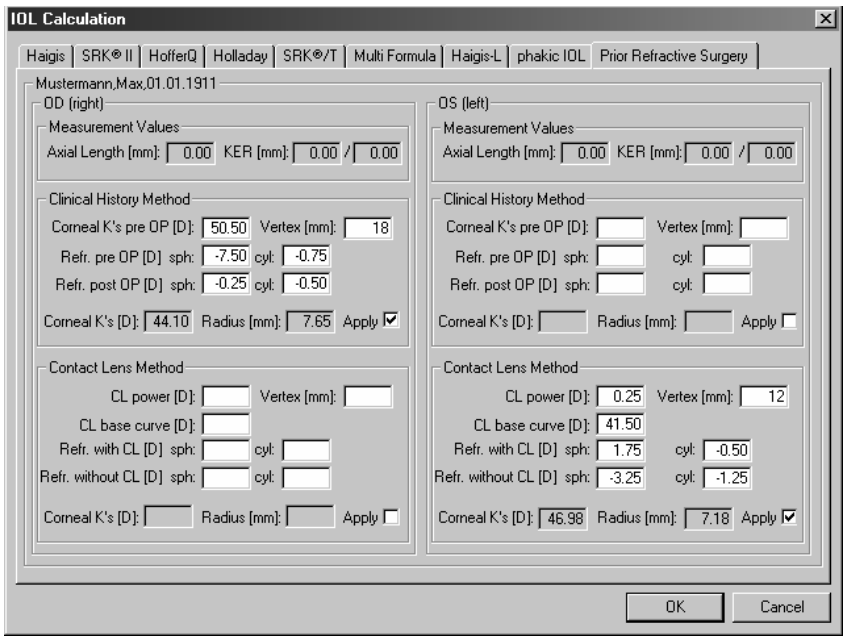


Fig. 39 IOL calculation window "Prior refractive surgery"

For the calculation of the IOL, the corneal K's selected by the examiner with ***APPLY*** will be transferred to the IOL calculation table. The IOL calculation can be started after selection of the biometric formula.



Warning
The calculated refractive power/radii values may not be edited in the IOL calculation window for the selected formula!

The corneal K's transferred to the IOL calculation are marked in the printout of the lens calculation with (**) and the calculation method.

Haigis L method

In contrast to the above-described methods of determining corneal refraction, the Haigis formula allows for surgical changes to the cornea and permits the calculation of the IOL from the **measured values** AL, Corneal K's and ACD.

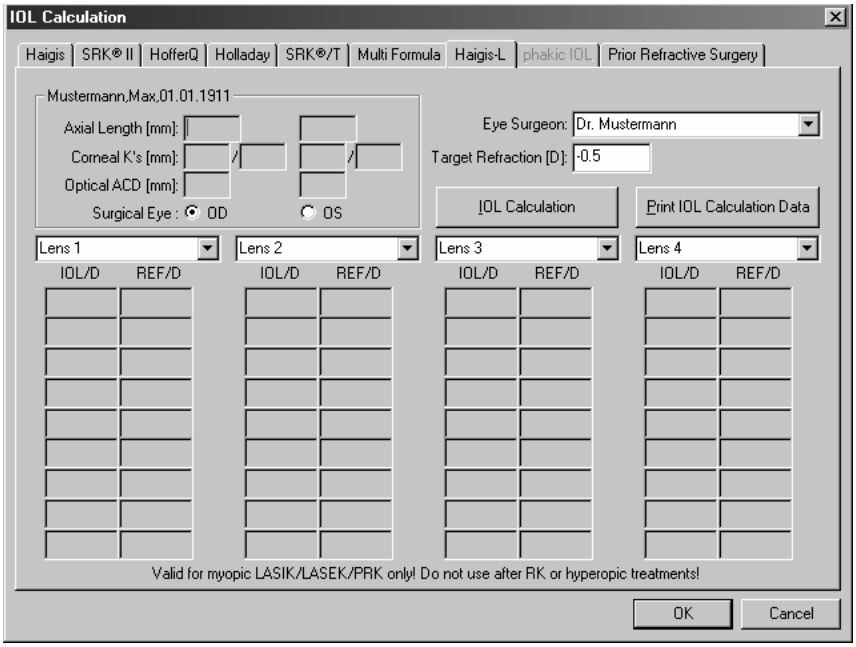


Fig. 40 IOL calculation window "Haigis-L"

Warning

The formula may only be used for eyes with myopic Lasik, myopic PRK and myopic Lasek.
Lenses by hyperopic Lasik/Lasek/PRK or myopic/hyperopic RK should never be calculated.
The corneal radii and axial lengths measured by the IOLMaster are required for the formula! The measured values cannot be edited here.

Calculation of phakic implants (optional)

This program component enables the thickness of phakic implants (iridocorneal anterior and posterior chamber angle-supported lenses) to be calculated.



Fig. 41 Lens model

Only spherical lenses can be calculated. In addition to the anterior chamber depth and corneal radii (corneal refraction) measured with the IOLMaster, the refraction for the appropriate corneal vertex (CVD) and lens model must be entered.

The manufacturer's IOL constants are used for calculating lens strength.

Warning
Please observe the manufacturer's recommendations for the phakic IOL employed with regard to choice of lens type and critical distance to the endothelium.

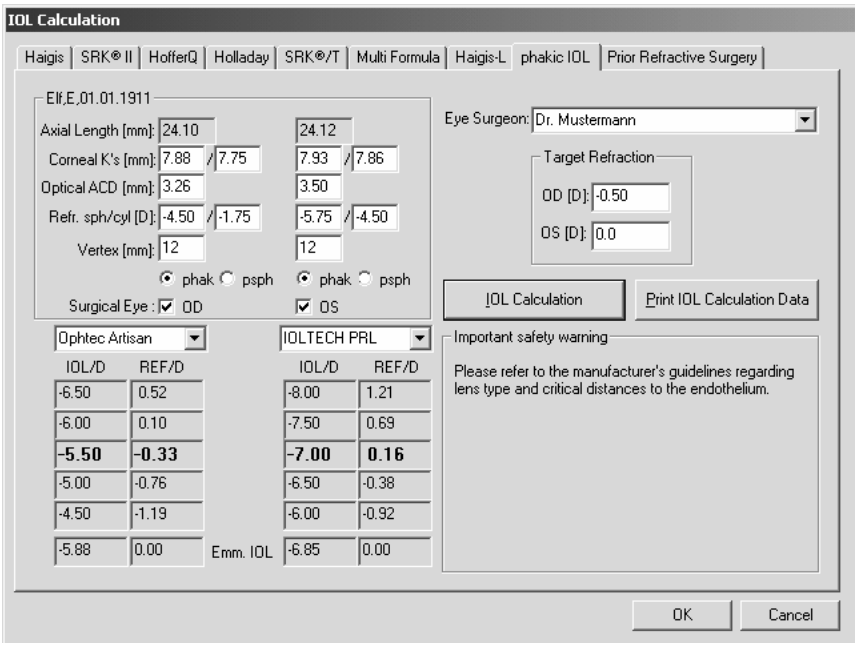


Fig. 42 Calculation of phakic implants

4-in-1 calculation

To compare the results of four different calculation formulae, select one of the four selection boxes for the desired formula.

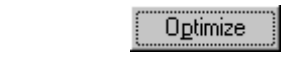
Select ***IOL CALCULATION*** to display the results. To print out the page with the results, press ***PRINT***.

Optimisation of lens constants

Selecting lens data

The lens data available in the database may be optimised by the following procedure.

- In the **Options** menu, open **User Database**. Select the respective eye surgeon and confirm your choice with ***OK*** (Fig. 44).
- Choose a lens. The input mask contains constants calculated from "A Constant Manufacturer" or previously optimised constants.
- Click on the ***OPTIMIZE*** button. The dialog box for the selected lens will appear and the lens constants can be seen in the **Basis** column (Fig. 43).



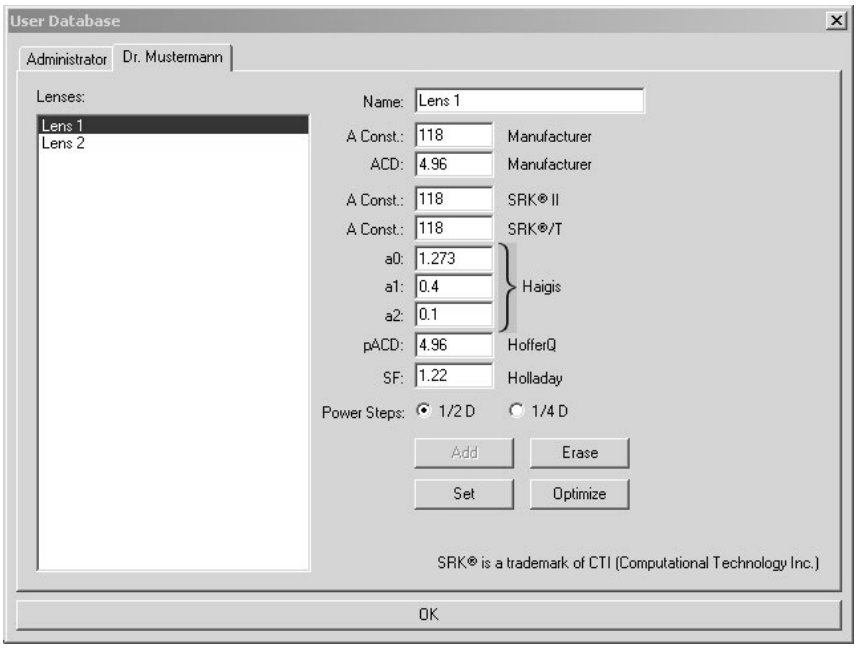


Fig. 44 Lens data in the "User Database" dialog box

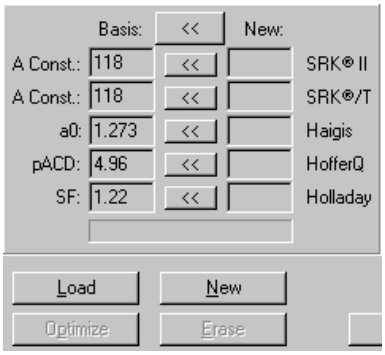


Fig. 43 Lens data in dialog box for selected lens

Loading existing data records



- Click on the ***LOAD*** button to load the data records of all patients available for optimization.

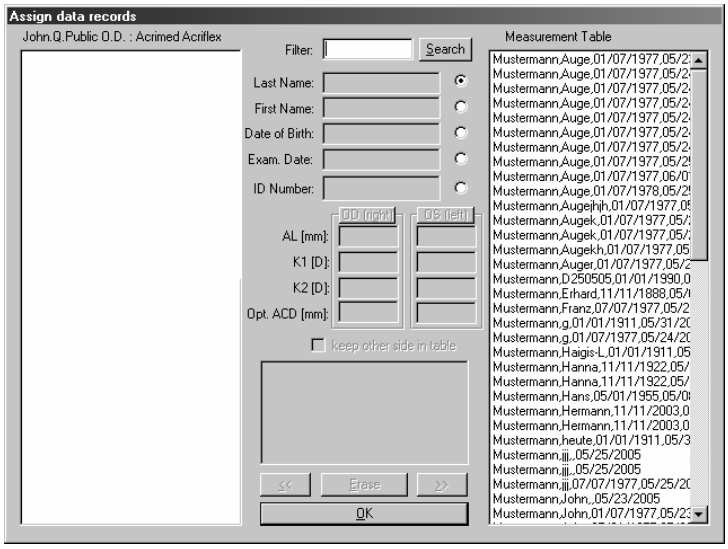
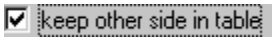


Fig. 45 "Assign data records" dialog box

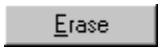
Special filter functions allow fast selection of patient data. The right column shows the list of all patients available for optimisation.











- Click on the desired patient data record in this list to select it.
- Select the eye to be used for the optimisation calculation. The fields below show the measurement data of the IOLMaster.
- If you wish the data of the other eye to be kept in the data table for further optimisation, activate **Keep other side** in the check box.
- Click on the **<<** button to load the selected data record in the left-hand table. These data records are intended for IOL optimisation.
- Transfer at least 11 data records into the left-hand table in this way.
- Click on the **>>** button to return the selected data record to the right-hand table if it is not to be used for optimisation, but should be kept for possible later use.
- Click on the ***ERASE*** button to irrevocably delete the data record to the right or left.
- When all the desired data records have been loaded into the left-hand table, press ***OK*** to return to the optimisation box (Fig. 44).
- Further patient records can be added to the left-hand list for subsequent additional optimisations.

☞ **Note**
The data contained in the database (right- and left-hand table) will not be deleted automatically and are thus available for later additional optimisations. A backup should be made at regular intervals by transferring data to an office management system or a printout.

Entering new data records

- To enter data records which do not exist on the IOLMaster result table, click on the ***NEW*** button.



This will bring up an input mask for creating a new data record to be optimised. However, this data record may be used for optimisation only, not for IOL calculation. Nor does it appear in the patient database.

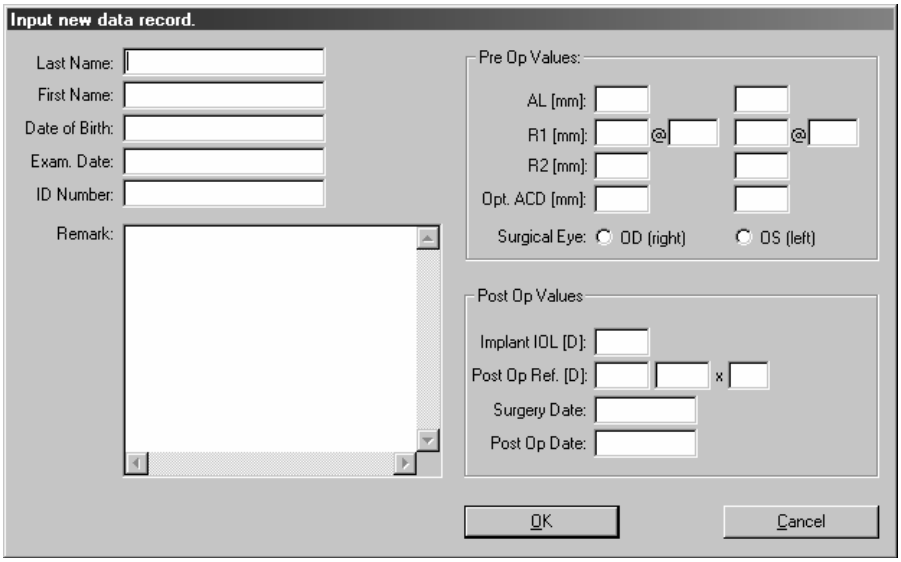


Fig. 46 "Input new data record" dialog box

Warning
Only data obtained from the IOLMaster may be entered in the fields for pre-operative data! When entering the refractive power, make sure that the same keratometer refractive index is set on the IOLMaster as on the keratometer used for the measurement (see page 33).
The entry of data measured on ultrasound devices will yield incorrect results!

Warning
The data records of patients who have undergone refractive surgery of the cornea should be excluded from optimisation.

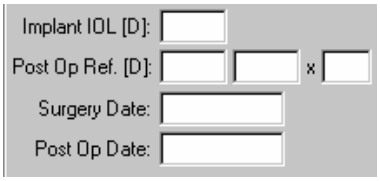
- Complete the entries in the input mask.

Note
The entry of the **Exam date** is mandatory!
Entry of **ACD** data, **Surgery Date** and **Post-Op Date** is optional.

Note
There should be a period of at least 8 weeks between the surgery and post-op dates. (This period, however, will not be checked!)

- If you wish to reject the entries made and return to the optimisation calculation, click on the ***CANCEL*** button.
- To confirm the new data record and add it to the list of data records to be used for optimisation, click on the ***OK*** button. The new data record is shown in the **Data Records** field. It is displayed in the list of data records.

Entering post-operative data



- Highlight the patient data record by clicking on it.
- In the **IOL (D)** box, enter the power of the implanted IOL.
- In the **Post Op Ref** box, type in the post-operative refraction.
- The entry of **Surgery Date** and **Post-Op Date** is optional. When entered, however, the data will be checked for plausibility.

Note
There should be a period of at least 8 weeks between the surgery and post-op dates. (This period, however, will not be checked!)

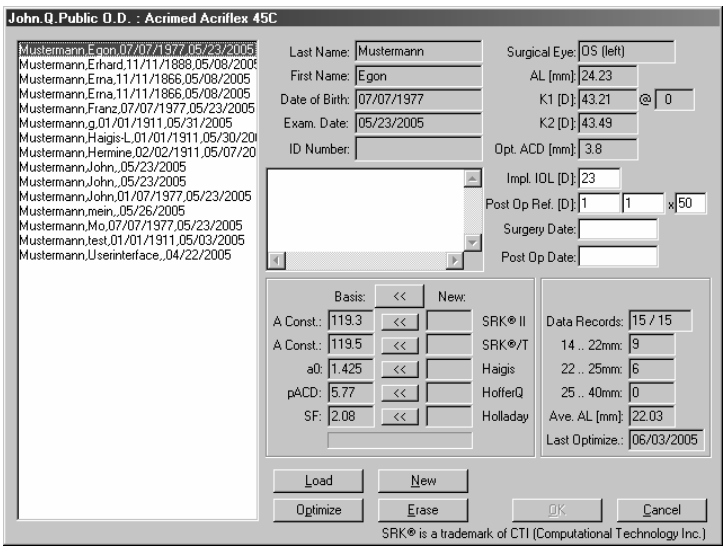


Fig. 47 "Assign data records" dialog box

- Complete all selected patient data records in this way. The number of data records containing IOL and post-op ref data and the total number of loaded data records is specified in the **Data Records** box.

The boxes beneath it show the number of data records in the specified axial length ranges.

Once all IOL and post-op data has been entered, the requirements for the optimisation calculation have been met.



- ❑ If a patient data record is highlighted in **red**, no IOL and/or post-op ref data has been entered for this data record or a measured value (AL or KER) is missing!
- ❑ If a data record is highlighted in **yellow**, no ACD values exist as yet: a0 (Haigis formula) will **not** be optimised with such data records!
- ❑ Patient data records appearing on a **white** background contain all the data required for optimisation.

☞ **Note**
Only the a0 can be optimised with the device software for the Haigis formula. For the optimisation of a0, a1 and a2 (more than 200 data records required) please send this clinical data to Carl Zeiss Meditec.



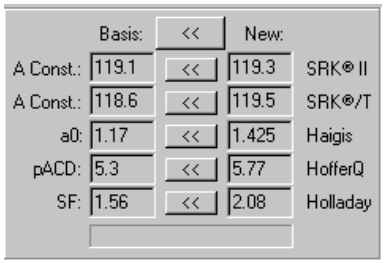


Fig. 48 Optimised lens constants

Starting optimisation

- Start the optimisation calculation by clicking on the ***OPTIMIZE*** button. Depending on the number of data records to be processed, the computing process may take some seconds.

The optimised lens constants will now be displayed in the **New** column.

☞ **Note**
Data records with an IOL power of 0 D will not be included in the optimisation process.

The optimisation calculation supplies lens constants for every patient's data record as they should have been on the basis of the measured values and results of surgery. The mean value (sum of all lens constants divided by the number of patients) and standard deviation are then calculated. Lens constants which are more than double the standard deviation are not included in the optimisation.

If less than 11 data records exist for optimisation or data records are rejected (0 D), "**---**" will appear in the **New** column. In this case the optimisation has failed.

Repeat the optimisation process, in this case with a larger number of data records, or perform several optimisations for various groups of eyes (e.g. short, normal and long eyes). This procedure also ensures a higher degree of accuracy in IOL calculation.

The resulting mean value will be displayed as an optimised constant. To obtain optimum constants, patients with pre-, intra- or postoperative complications which could affect the refraction state should be excluded.

☞ **Note**
The displayed a0 value does not take into account the data records highlighted in yellow!

- To reject the last optimisation run, click on ***CANCEL***. In this case, the optimised constants will not be saved to the lens data base, even if a new data record has been entered.
- Confirm the newly optimised lens constants by clicking on the **<<** button to the right of the **Basis** field. In this case, all optimised constants will be accepted. If you want to accept a special constant only (e. g. a0), click on the **<<** button right of this constant.

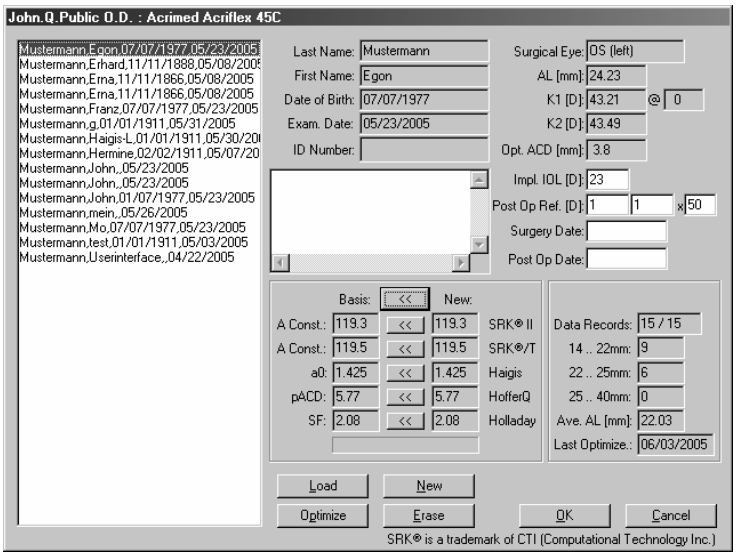


Fig. 49 New data record has been added

- Click on ***OK*** to return to the **User Database**. Optimised lens constants will only be saved to the lens database and for use in future IOL determination if they are confirmed with ***OK***.
- Click on ***OK*** to return to the IOLMaster main module.

New patient



If you have completed measurements on one patient and wish to continue with another patient, click on

- the ***PATIENT MANAGER*** icon or
- the ***N*** button.

The readings of the previous patient to the left and/or right will be stored and removed from the display. The Patient Manager appears and new patient data can be entered.

☞ **Note**
Data is available in the internal database for the period preset in the **Database** box under **Program Settings** (see page 32).

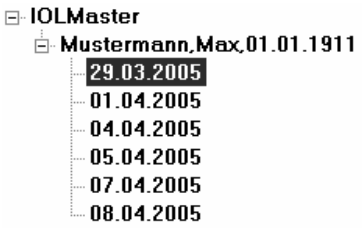
After entering new patient data and confirming with ***<ENTER>*** or ***NEW***, the device switches to Overview (OVW) mode

☞ **Note**
The above order of measurements is only an example. You may also run the above-described measurements in a different order. The only requirement is that the keratometer measurement precedes the anterior chamber depth measurement.

Working with the Patient Manager

The IOLMaster keeps an internal patient file. All data is stored here and can be retrieved (viewing, post-treatment, printing).

☞ **Note**
The file is not designed for archiving patient and measurement data.

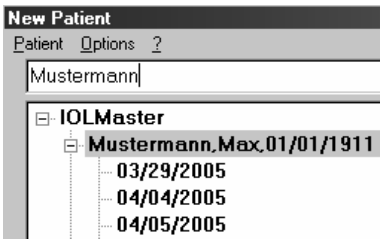


The database field is structured similar to Windows Explorer (see Fig. 25, left side). A **+** sign at the branch indicates that the database already contains measurement results for this patient.

- Click on **+** to display the treatment data for the last measurement(s). To close, click on the **–** sign.

The data records are sorted alphabetically by last name.

Use the Search textbox to quickly access a data record. Place the cursor in this box and type in the desired last name to list all relevant data records. The following letters of the name can also be entered; this ensures fast access to the desired data record.



On repeat visits, data can be instantly transferred to the input area by clicking on the patient's name.

To take a new measurement, click the ***NEW*** button or use the keyboard shortcut ***<ALT> +< N>***.



Retrieving a reading from previous measurements

The system permits the review of data records of previous sessions.

- Click on the **+** sign in front of the patient's name.
- Use the cursor to mark the examination date being sought.
- To view the measured data, press the ***OPEN*** icon, use the keyboard shortcut ***<ALT>*** + ***<F>*** or double-click on it. The data record is now ready for further editing. However, no new measurements can be taken.
- Automatic right/left detection is deactivated. To select a side, click the cursor on the appropriate display or press the ***<R>*** or ***<L>*** key.



Deleting a patient/measurement

- To delete a patient from the patient list, highlight the name and press ***<DEL>*** or select **Erase** from the **Patient** menu.
- Confirm the delete action with ***YES***. Personal data and individual measurements for this patient will be irrevocably deleted in the Patient Manager. The numerical measurement data will still be available in the database for optimisation of lens constants.





Note
If you are working with the option **User login with password**, you may only delete patient data if you have the appropriate rights (see User Manager on page 35).

If a measurement date is highlighted, only the data for this examination date will be deleted. The patient name and other measurement data will be retained.

☞ **Note**
In **Options – Setup – Program Settings** you can set the number of days after which a data record is automatically deleted (5 to 365 days).

Renaming a patient



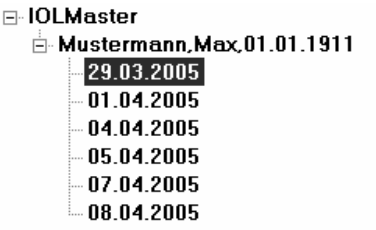
To edit the last name, first name, date of birth or ID No. of a patient, follow this procedure:

- Highlight the patient's name and press ***<CTRL>*** + ***<U>*** or select **Rename** in the **Patient** menu.

The patient data can be edited in the dialog box which now appears.

Once the renaming has been confirmed, patient data for all measurements will be changed. Measurement results cannot be renamed!

- Confirm the changes with ***RENAME***.



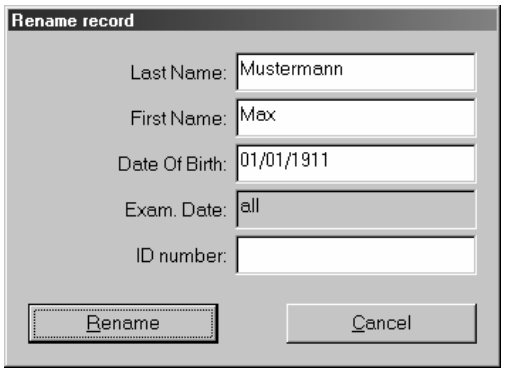


Fig. 50 "Rename record" dialog box

Transmitting/exporting data (optional)

Patient data can be exported to
- connected office administration systems or personal computers
- a USB storage medium or a CD-TW.

The data is then available for further processing.

☞ **Note**
Transmitting/exporting does not work in the Patient Manager, only in measurement modes!

Exporting data to another system

❑ Data can only be exported to office management systems by the supplier of such systems. Please contact the respective supplier.

❑ The appropriate accessories are required for exporting to a connected Windows-based personal computer. These can be obtained from Carl Zeiss Meditec. They include a serial cable (null modem, female/female connector) and software (on CD ROM) to be installed on the PC. Data is imported to a database on the PC. From there, data can be exported to other file formats. The graphs of axial length measurements are made available in JPEG format.



- To export data press the ***<S>*** key (not in Patient Manager!) or the ***SEND*** button.
  The data will be exported.

☞ **Note**
The PC must have been switched on and the software for data receipt started. A progress bar will be visible on the IOLMaster screen. Data can be archived on the PC or processed in the appropriate form.

☞ **Note**
The export of measured values depends on whether the additional software Option A plus is installed:
- Without Option A plus: only the measured values and the marked IOL will be exported.
- With Option A plus the measured values and all calculated lenses will be exported (see page 32 f), depending on the setting in **Program Settings/Export**.

Exporting data to a storage medium

- Select the desired storage medium in the menu **Options** – **Setup** – **Program settings/Export** (see page 34).

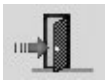
☞ **Note**
If you wish to export to a CD-RW, you must insert a formatted CD-RW into the drive. The CD-RW must be formatted elsewhere (e.g. office PC) in UDF format. Alternatively, use one of the formatted CD-RWs as supplied. For exporting to an USB flash drive the latter should enable at least a transfer rate to USB-1.1.



- To export data to a USB storage medium or a CD-RW press the ***<X>*** key or the ***EXPORT*** icon.

Data will be available in a text file conforming to the export settings (see page 34) for archiving and data analysis.

Switching off the device



- When all measurements have been completed, exit the program by pressing the ***EXIT*** icon or ***<E>*** key.
- Then press ***OK*** or ***<ENTER>***.
  The data of the current (last) patient will be saved automatically.
- Switch the device off at the power switch.
- Wait until the switch lamp goes off before pulling the power supply plug or switching off at the main room switch.

☞ **Note**
The device may not be switched on again until the switch lamp goes off!

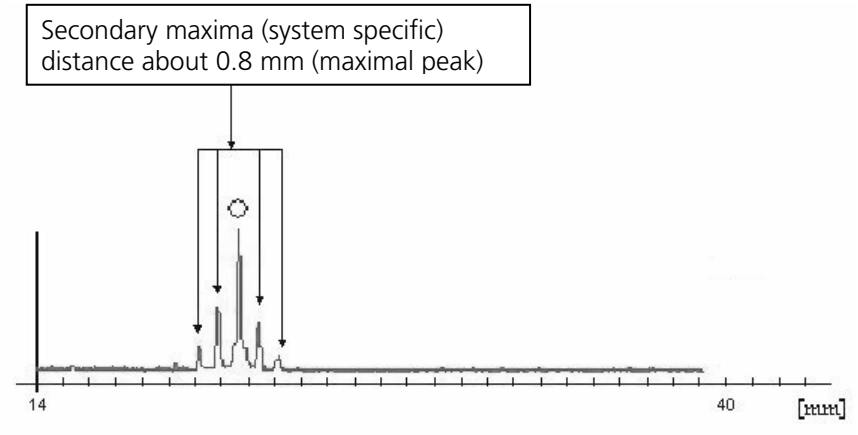


Caution
If the device is switched off at the power switch while it is in operation, the program will quit automatically before the device shuts down. It is thus important to wait until the switch lamp goes off before pulling the power supply plug or switching off at the main room switch.
If the device is unplugged or switched off at the main room switch while the device is still running, the program cannot quit and the operating system cannot be shutdown properly; this can lead to loss of saved data and/or defects in the devices's control software. This does not present a hazard to patients or the operator.

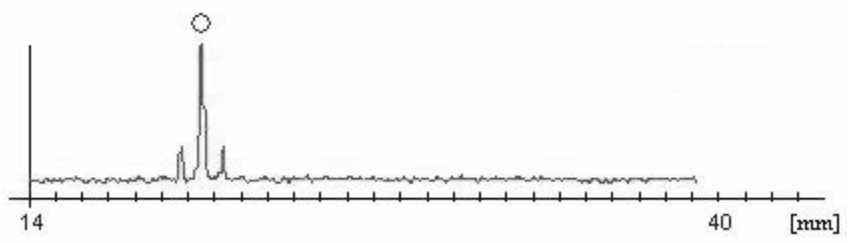
☞ **Note**
The procedure described below does not apply in the case of breakdowns (see page 101) or if the device does not respond to your input! If this occurs, switch off the device immediately and pull the power supply plug! Label the device as being defective and call Carl Zeiss Service.

Signal curves of axial length measurements

Valid signal curves

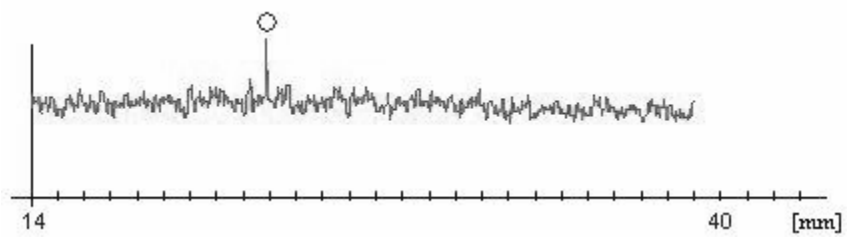


- Very good signals (signal-to-noise ratio > 10)
- Several secondary maxima visible (system specific)
- Clear media, patient correctly fixating
- Slight ametropia



- Clear signal (SNR display GREEN)
- Secondary maxima visible
- Relatively clear media





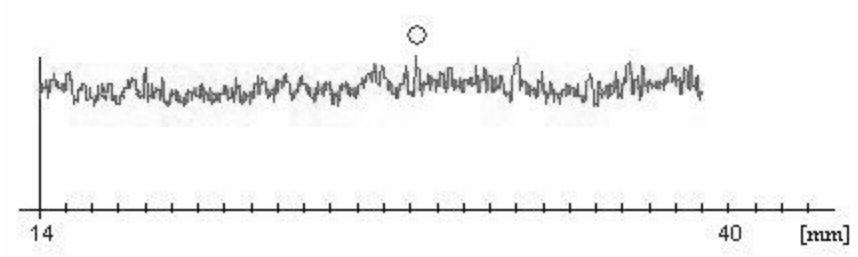
- Signal in "Borderline SNR" (uncertain) range (SNR display YELLOW)
- Steep rise of measuring signal
- Such readings are accompanied on the display by an exclamation mark and the message "Borderline SNR" (uncertain reading).



Warning
This reading may be used after verification and comparison with other data from this series of measurements.



Recognition of maladjustments on the graph





- Low signal (SNR display RED)
- Error message is displayed.
- The measuring signal cannot be clearly distinguished from the noise.

Possible reasons:
- unsteady (non-fixating) patient,
- strong ametropia,
- dense medial opacity along the visual axis.

Repeat the measurement!
Ask the patient to fixate steadily.

Measuring errors with pseudophakic eyes

In the measurement of pseudophakic eyes and with specific intraocular lenses (e.g. Acysof), two peaks may appear. The first higher peak is a side maximum of the IOL, while the second peak is produced by the retina. In this case, manual correction of the axis length is necessary.
It is expedient to measure at a number of different points.

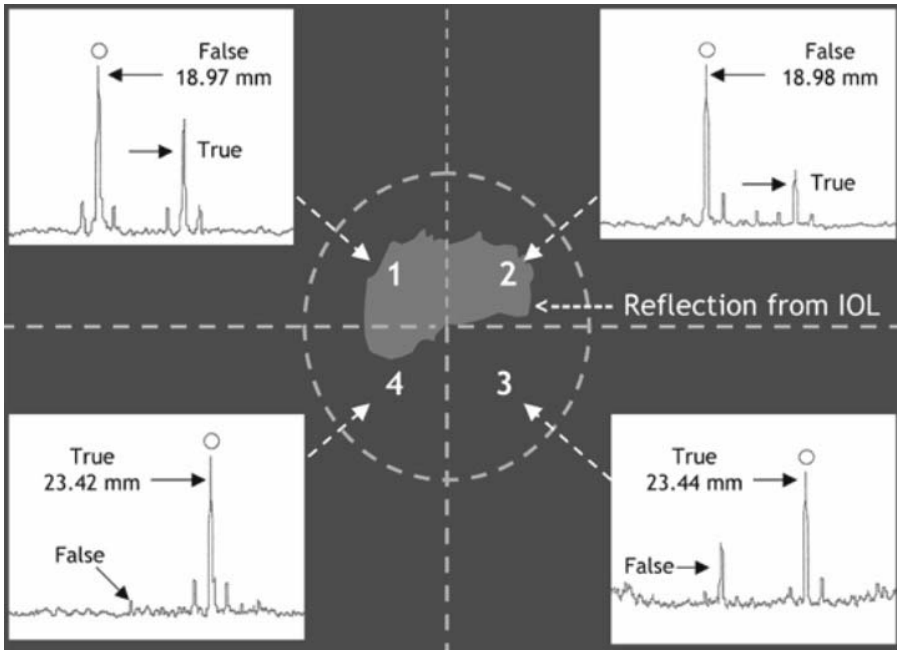
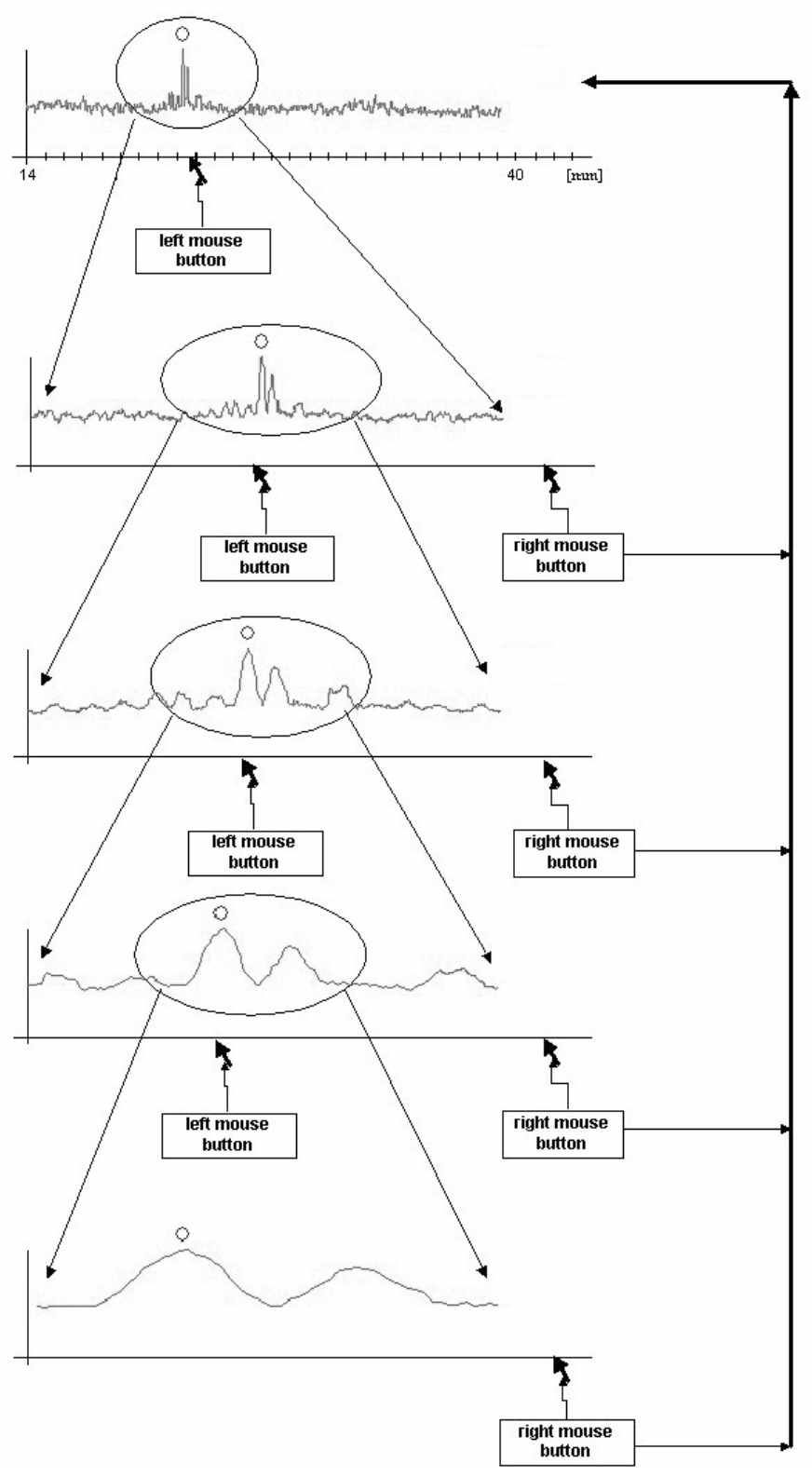


Fig. 51 Axial length measurement of pseudophakic eyes; double peaks with certain IOL; Source: W. Hill, Mesa, Arizona

Zooming the graph display



The system allows zooming the graphs in 4 steps to improve the presentation of signal curves:

- Move the cursor on the longitudinal axis (x-axis) to the desired centre of the zoomed image and press the left mouse button. This procedure may be repeated four times.
- To return to the original view (zooming out), place the cursor at any position on the longitudinal axis and press the right mouse button.

Note
In zoomed views, the axial length scale is not visible!

Post-run editing of axial length measurements

The results of axial length measurements must be interpreted on the basis of the signal-to-noise ratio and the appearance of the graphs (cf. *Signal curves of axial length measurements*, page 75).

The manipulations described here can be performed on the individual measurements, but have no influence on the composite signal. Manipulations are therefore only expedient on the composite signal.

For simplification reasons, the illustrations below do not show the video image.

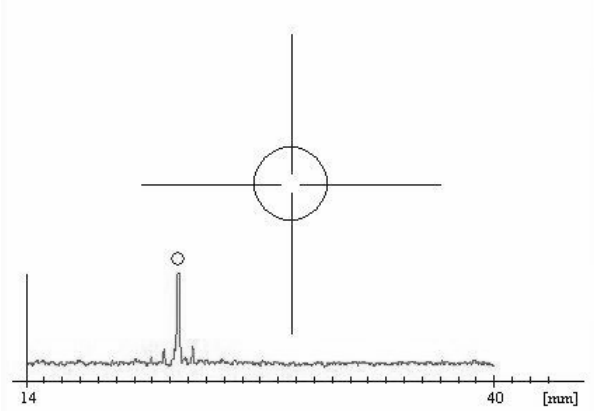


Fig. 52 Presentation of the graph of the third axial length measurement without video image

SNR categories





The SNR is automatically analysed while the system is internally calculating the axial length from the interference signal.

SNR display at GREEN --> reading is valid.

SNR display at YELLOW --> Reading is uncertain ("Borderline SNR").

The signal-to-noise ratio may be low for the following reasons:
- Dense medial opacity along the visual axis,
- restless patients,
- alignment of device to patient eye is not optimal,
- very high ametropia (> 6 D),
- corneal scars,
- pathological changes in the retina.

☞ **Note**
In this case, "Borderline SNR" or "uncertain" does not mean an incorrect result, it is only to remind you to verify this measurement!

Should multiple peaks occur in the composite signal, it may be possible to identify the "correct" signal peak by comparison with the individual readings for this (and the other) eye and the anamnesis. See sections *Signal curves of axial length measurements*, page 75 and *Shifting the measuring cursor*, below

SNR display at RED (reading should not be used)



It is marked on the display as a measuring error.

This means that the true measuring signal does not stand out sufficiently from the noise. As a rule, such readings are not usable and should be rejected. They can be deleted from the list by highlighting them and pressing the ***<DEL>*** key.

The reading may be transferred to the list by clicking on the measuring cursor (white dot). Before doing so, ensure that the readings are consistent.

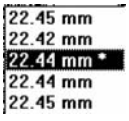
Shifting the measuring cursor

The measuring cursor (white dot) is automatically placed on the centre of the signal peak with the highest absolute amplitude. The corresponding axial length value is displayed beside the graph and in the display field. The SNR is calculated and displayed for this signal peak. The measuring cursor is placed in the centre between the regions corresponding to half the maximal amplitude. If the signal curve is symmetrical (Gaussian curve), the cursor is positioned exactly above the maximum of the signal.

There are two ways to shift the measuring cursor to another peak; it is recommended that these manipulations be carried out in a zoom view of the measurement curve.

1. Automatic positioning over a "distant" peak:

- Place the arrow cursor on the white dot, hold the left button depressed and move the measuring cursor over the other peak. For easier orientation, a vertical blue line will appear below the white dot. This line can be dragged with the cursor.
- When the button is released, the measuring cursor automatically snaps in over the desired peak.



The display will show the corresponding axial length and SNR (always smaller than the maximum SNR found automatically) and the recalculated value will appear in the display field denoted by an asterisk (*).

Example:

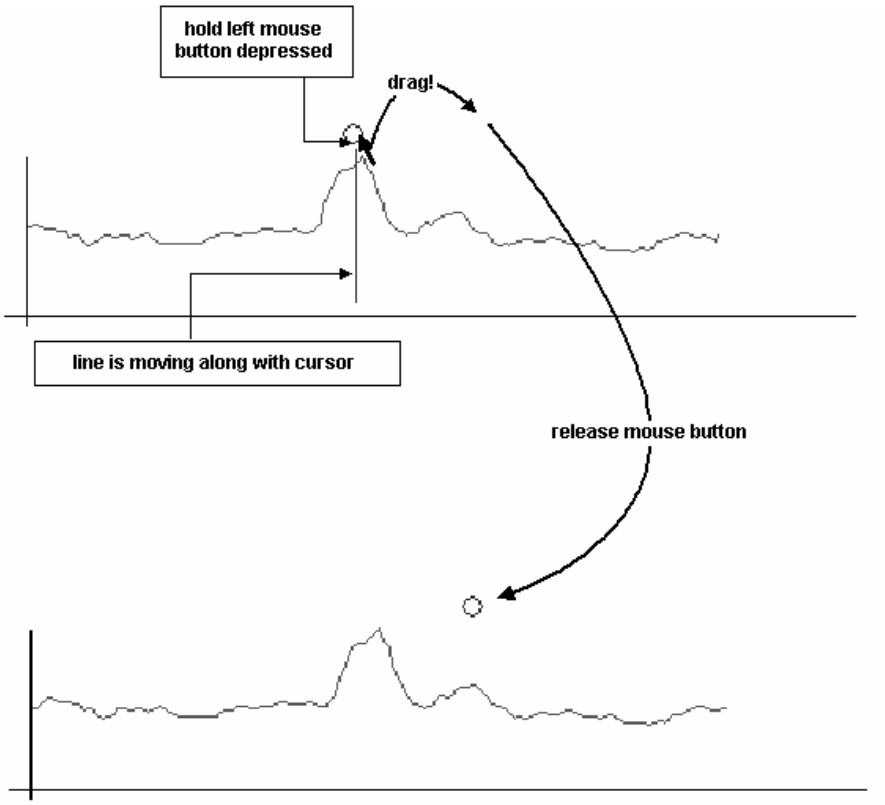


Fig. 53 Moving the measuring cursor to a different peak (signal curve zoomed in 3 times)

Note:
This manipulation will work only if the measuring cursor is moved across the (local) maximum of the desired target peak. This procedure is necessary for the search algorithm to reliably find the desired peak without returning and snapping in to the original (higher) peak.
Closely adjacent peaks (double peaks) cannot be separated by this automatic method unless the curve adjoining them drops down below a value which is less than half the amplitude of their maxima.

☞ **Note**
While the measuring cursor is being dragged, the original reading and SNR are always displayed alongside the composite signal. The new axial length value and corresponding SNR will be calculated and displayed only when the button is released.

2. Fine-shifting the measuring cursor

☞ **Note**
This manipulation should always be performed in a zoomed view!

- Proceed as described above under item 1, but use the right button to drag the measuring cursor. This way the automatic peak detection is deactivated and the white dot can be positioned at any point over the measuring curve.
- When the button is released, the current axial length and the new SNR will be calculated and displayed.

This kind of manipulation is advisable with closely adjacent double or triple peaks.

Here again, the recalculated axial length is shown in the display field with an asterisk (*).

Note:
Even if the manipulations are undone with the measuring cursor (by moving it back to the automatically found maximal peak) and the measured value agrees with the original one, the asterisk after the measured value will remain, indicating that the curve has been deliberately manipulated!

The described manipulations of the measuring cursor may be performed both in axial length measurement mode (after the current individual measurement) and in post-run editing mode.

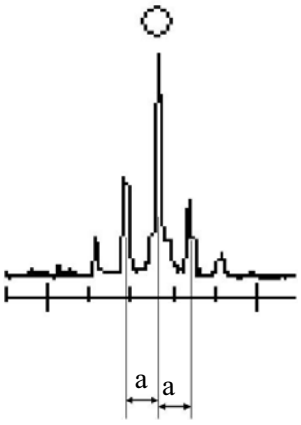
Interpretation of axial length measurements

As a rule, an interference signal is produced if the measuring light is reflected by the retinal pigmented epithelium of the eye. This signal is utilised for axial length measurements.

☞ **Note**

Ultrasonic biometrical instruments measure the axial length as the distance between the cornea and the inner limiting membrane, because the sound waves are reflected at this membrane.
To ensure that the measured values obtained with the IOLMaster are compatible with those obtained through acoustic axial length measurement, the system automatically adjusts for the distance difference between the inner limiting membrane and the pigmented epithelium. The displayed axial length values are thus directly comparable to those obtained by immersion ultrasound! Deviations may nevertheless occur between the displayed axial lengths and ultrasonic readings (particularly in the applanation procedure). At this point, the importance of re-personalising the "lens constants" should be stressed, because the IOLMaster is based on a new, more precise measuring technology.
Refer to the specialist literature and publications by the originators of the IOL formulae regarding the personalisation of constants.

Updated information is available in the Internet at:
http://www.meditec.zeiss.com/iolmaster and/or
http://www.augenklinik.uni-wuerzburg.de/ulib/



a ≈ 0.8 mm

Fig. 54 Undisturbed measurement signal with secondary maxima

With an optimally aligned device, relatively clear eye media and slight ametropia (< 6 D), the secondary maxima will be detected symmetrically on each side of the actual measuring peak. These are caused by the measuring light source used and maintain a constant distance of approx. 0.8 mm to the measurement signal and to each other, irrespective of the specific circumstances of the measured object. For this reason, the secondary maxima are similarly always visible in measurements of the supplied test eye.

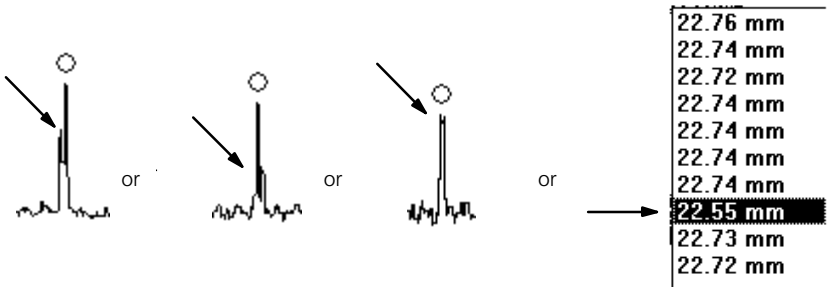
The IOLMaster measuring system is capable of resolving fine structures on the fundus of the eye.

Depending on the anatomical conditions of the measured eye, the measuring beam may also produce interferences when reflected at the inner limiting membrane and/or the choroid.

Indications of this are:

- broader (smeared) signal peaks of the measuring curve,
- variations of approx. 150 to 350 µm in axial length data in one measurement series and
- display of "Evaluation" in place of the mean value (composite reading).

Examples:



Such measuring curves or measurement series require immediate verification, either between individual measurements (in ALM mode) or in post-run editing (without the patient in front of the device). Interpretation or post-run editing should always be performed with the help of the zoom function!

☞ **Note**

The resolution of fine retinal structures is clearly distinguishable from the previously mentioned secondary maxima, which are further away from the multiple peaks and symmetrical to them. The distance between the maximum peak and internal limiting membrane or choroid is 350 µm (whereas the secondary maxima are about 800 µm from the maximum peak!).

Signals from the inner limiting membrane (ILM)

The measuring beam is relatively often reflected at the inner limiting membrane, likewise producing an interference signal. The respective signal peak lies to the left of the actual measurement peak (to the shorter axial lengths). The distance of the peak generated by the reflection on the inner limiting membrane from the measurement peak is between 150 and 350 µm. Both peaks can be observed separately in a zoom view of the graph.

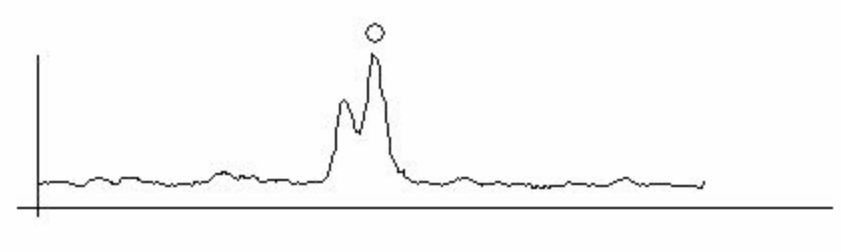


Fig. 55 Double peak produced at inner limiting membrane (triple zoom)

Usually, the signal amplitude of the peak from the inner limiting membrane is smaller than that of the interference on the pigmented epithelium. In such a case the automatic algorithm finds the correct axial length.

Warning
Never move the measuring cursor manually to the (left) peak produced by the inner limiting membrane (see above)!

In rare cases the amplitude of the signal from the inner limiting membrane may be higher than that of the reflected light from the pigmented epithelium. In this case, the automatic peak detection will recognise the signal from the ILM.

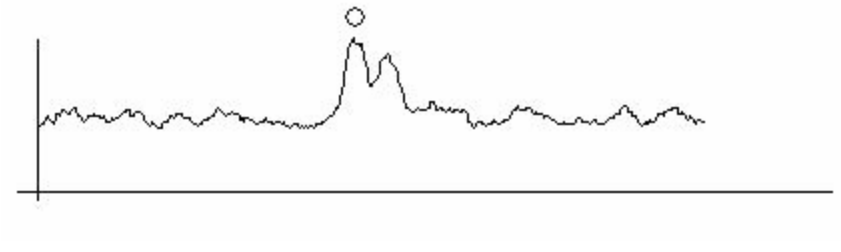


Fig. 56 Signal curve with higher signal from inner limiting membrane (double zoom)

In measurement series, such individual measurements stand out by deviations in the range of approx. 150 to 350 µm towards shorter axial lengths. The reading can be corrected by dragging the measurement cursor in the composite signal to the lower peak (that of the pigmented epithelium). This manipulation is only permissible in the context of the single signals of this series of measurements!

Signals from the choroid

Triple peaks

In rare cases, the measuring beam may also be reflected by the vessels of the choroid.

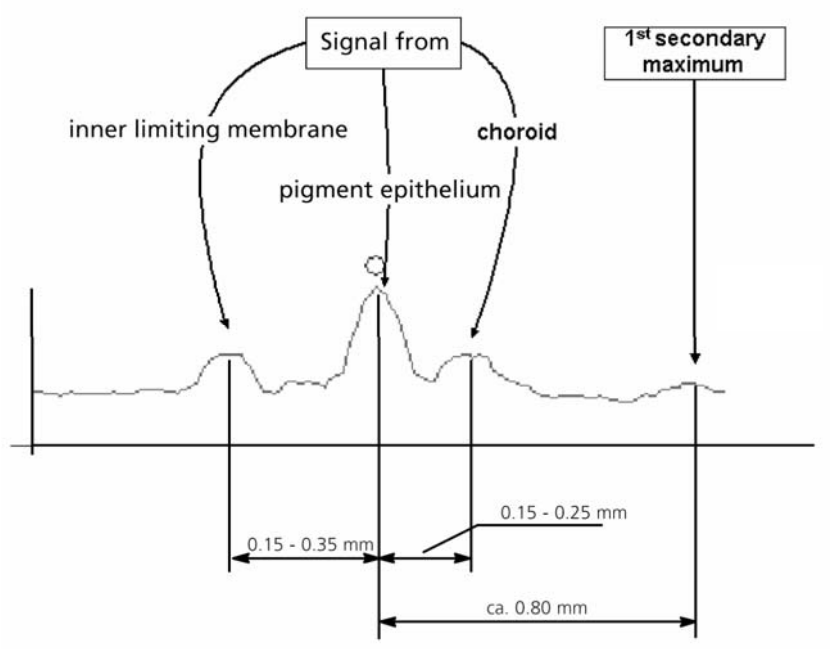


Fig. 57 Rare triple peak (triple zoom)

The measuring peak produced by the choroid appears shifted towards longer axial lengths by approximately 150 to 250 µm from the peak of the pigmented epithelium.

In the above example, the signal from the RPE (middle peak) has the highest amplitude. The automatic peak detection system has correctly recognised this measured value as the axial length, so that the measuring cursor may not be moved.

This type of rare triple peak clearly differs from the secondary maxima produced through the light source by the distance from the RPE reflected peak.

In very rare cases, depending on the anatomical conditions of the measured eye, the signal produced by the pigmented epithelium may not be the one with the highest amplitude.

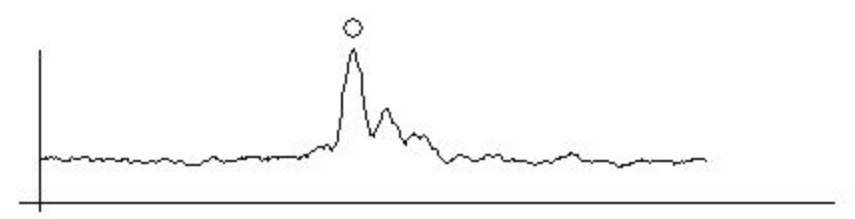


Fig. 58 Triple peak (double zoom)

The automatic peak detection system will find an axial length value that is too short by approximately 150 to 350 µm.



Following the comparison of all measured values and curves for this eye, the measuring cursor must be moved manually to the middle (smaller) peak produced by the RPE. This measured value is thus corrected and shown in the display field with an asterisk.

Double peaks

In very rare cases signals may be produced by both the pigmented epithelium and the choroid.

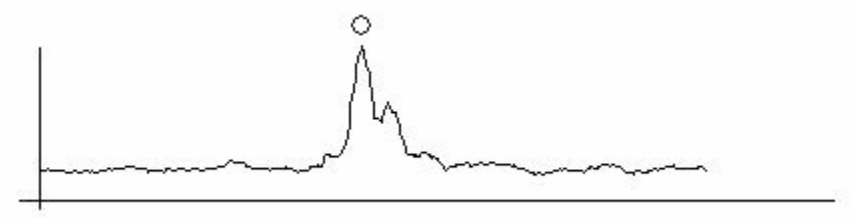


Fig. 59 Double peak produced by pigmented epithelium and choroid (double zoom)



Here again, the automatic peak detection system has placed the measuring cursor at the correct position, as the (correct axial length) signal from the pigmented epithelium has the greater amplitude. The measuring cursor may not be moved.

Note

Such a curve may only be evaluated correctly by viewing all measuring curves of this eye. Such a curve must be clearly distinguished from double peaks produced by the inner limiting membrane and the RPE (see Fig. 55)! It may be advisable to perform further individual measurements. Up to 20 measurements may be taken on one day.

How to adjust the measuring marks

Ask the patient to relax and look at the yellow fixation light. If the patient cannot see the fixation light, he or she should look straight ahead into the device.

☞ **Note**
The peripheral infrared measuring marks will be invisible to the patient. (However, in a darkened room an attentive observer may perceive the measuring marks as faint red dots when looking into the projectors of the keratometer.)

When adjusting the device, make sure that all 6 peripheral points are visible and located in the field between the two auxiliary circles, as closely as possible to the centre of the display. The images of the measuring marks on the display must be optimally focused by varying the distance between patient and device. The images of the measuring marks should be circular or ellipsoid. Provided the traffic light function has been activated, a green light will appear when the measurement setting is optimum.

To improve the reflectivity of the cornea, it is advisable to ask the patient to close and open the eyes several times. This replenishes the tear film and improves the imaging of the measuring marks (on a regular cornea). The appropriate reminder will appear below the video image when the keratometer mode is activated.

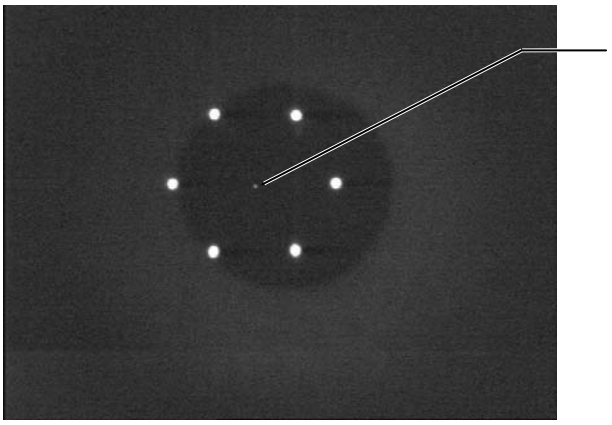


Fig. 60 Optimally aligned device (shown without cross hairs and auxiliary circles; the central fixation point is distinctly fainter than the measuring points)

Note
Depending on the reflectivity of the cornea, the image of the fixation point may be barely visible. This is irrelevant for the calculation of the corneal curvature, as the position of the fixation point will not be evaluated.

Measuring errors

The "Error" message may have two basic causes:

- ❑ The results of the internal individual measurements vary by more than 0.05 mm (very rare, defocused device).
- ❑ The measuring marks are either indiscernible or not recognised as such.

(The marks not recognised will be shown on the screen after measurement).

The possible reasons for this are described below.

Misadjustments

Defocused device

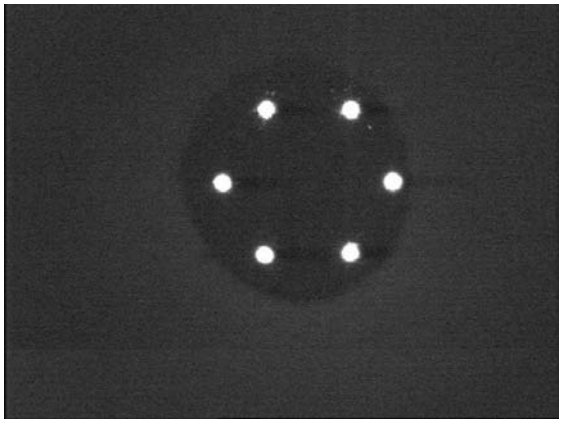


Fig. 61 Image of a defocused device

Cause

The images of the measuring marks are too large, because the device is defocused. The system cannot calculate a measured value and "Error" appears in the display field.

Remedy

The measurement can be retaken after correcting the focus adjustment to minimise the peripheral mark size. Sometimes, with exactly adjusted focus, small circles (like haloes) may be visible around the six peripheral measuring points. In this case, focusing is optimum.

Concealed measuring marks

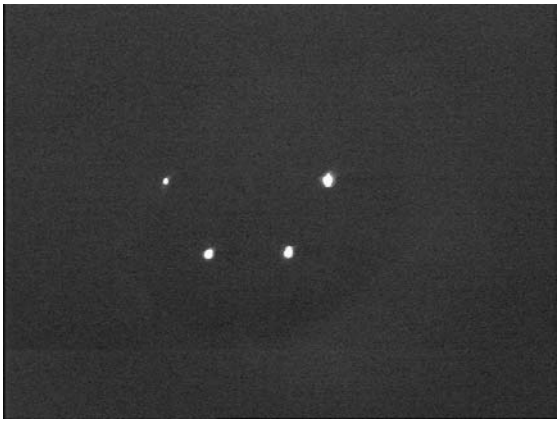


Fig. 62 The upper two measuring marks are concealed by the eyelid

Cause

"Error" appears the display field. This error may also occur if the patient blinks during measurement (0.5 s). This is particularly the case with restless or anxious patients.

Remedy

Ask the patient to open his or her eyes wide and repeat the measurement. If measurement is still not possible, gently lift the upper eyelid, as is usual in tonometry.

Warning
Take care not to deform the eyeball! Pressure on the globe causes a deformation of the cornea and results in incorrect radius and refraction measurements.

Other findings

Pseudophakic eyes

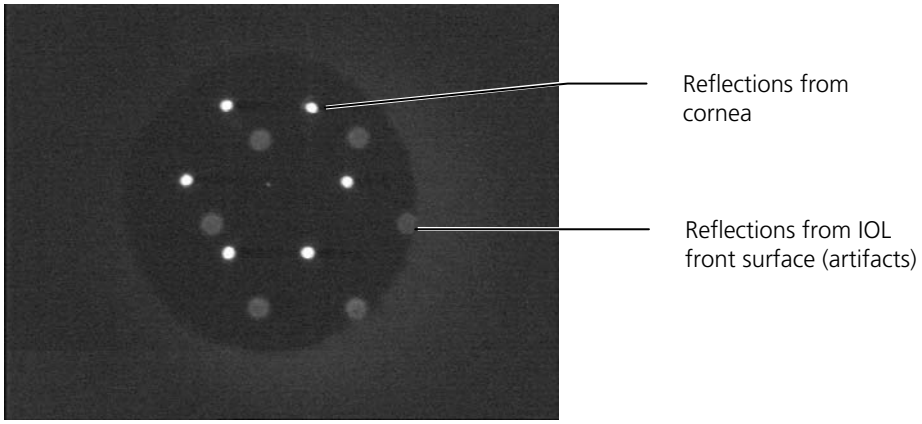


Fig. 63 Pseudophakic eyes

Cause

In the measurement of pseudophakic eyes, images of the measuring marks may be visible at the front of the intraocular lens beside the reflections of the cornea.
The reflections from the IOL are fainter and lack definition.

Remedy

Try moving the device approximately 1 mm away from the patient's eye (defocusing) and take the measurement. The images produced at the cornea will now be slightly larger, while the artifacts of the IOL become fainter, such that the evaluation process may not identify them as measuring points; a measurement is then possible. If this procedure does not succeed, the corneal curvature cannot be measured.

Dry eye

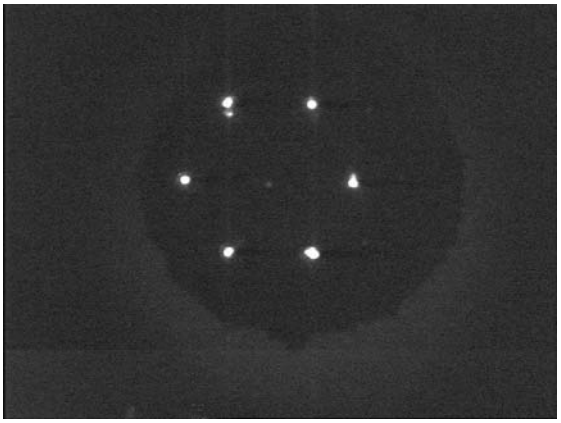


Fig. 64 Multiple reflections produced by a dry eye

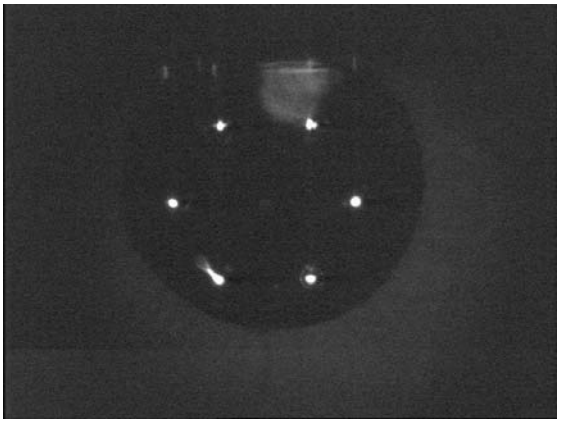


Fig. 65 Light trail (bottom) due to a dry eye (at top additional disturbance by an eyelash)

Cause

If the tear film is suddenly interrupted, the reflectivity of the cornea will be greatly reduced at these points and the cornea will scatter the light more strongly. If a measuring mark is projected to such a region, the otherwise circular or ellipsoid image of the measuring mark will become irregular. Irregular marks and/or multiple reflections will form. In this case, a precise measurement of the corneal curvature will not be possible. The results will fluctuate or the "Error" message will be displayed.

Remedy

Ask the to patient blink several times to replenish the tear film on the cornea, then take the measurement immediately or use a tear supplement to prevent rapid drying.

Irregularities of the corneal surface (scars)

Cause

Scars and local irregularities on the corneal surface impair the imaging quality of the measuring marks. Depending on the extent and location of the artefacts, measuring errors may occur.

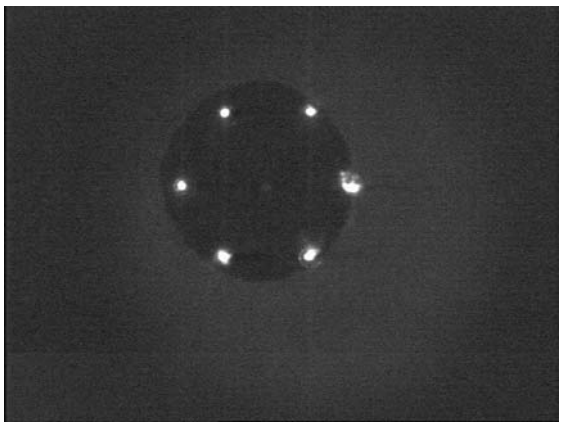


Fig. 66 Local corneal scar impairing right measuring point

Remedy

Try to position the measuring mark adjacent to, above or below the scar by slightly displacing the device relative to the eye, then take a measurement. In such cases, it is advisable to repeat the measurement several times. Depending on the degree of irregularity, fluctuations or measuring errors may occur.

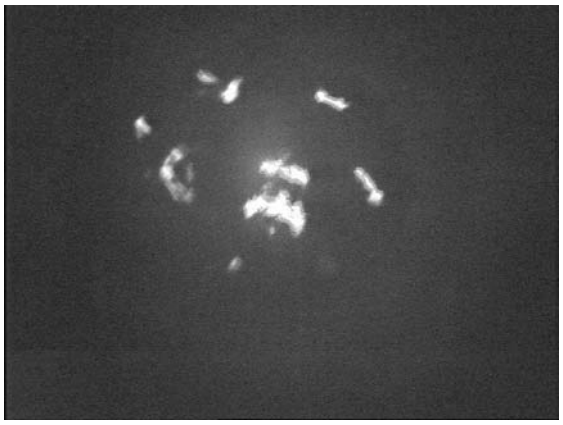


Fig. 67 Condition following keratoplasty

☞ **Note**
In this case, keratometer measurements cannot be taken with the IOLMaster.

How to adjust the device

Ask the patient to relax and look at the yellow fixation light. If the patient cannot see the fixation light, he or she should look straight ahead into the device. When the anterior chamber depth mode is turned on, the system automatically activates the lateral slit illumination. The illumination always originates from a temporal direction.
The slit illumination will appear subjectively bright to the patient. The measured values of the light load (see *Technical specifications*, page 109), however, are smaller by several orders of magnitude compared to slit lamp examinations.
When the measurement is taken, the slit illumination will start to flicker. The patient should continue to look at the yellow fixation light, not the slit.
(Note: Although it is not dangerous to look into the slit projector, this leads to erroneous anterior chamber depth values.)

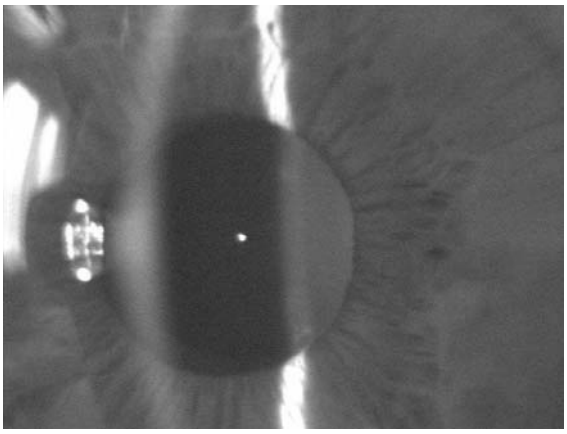


Fig. 68 Optimally adjusted optical section for anterior chamber depth measurement

An image similar to that of a slit lamp (optical section through the anterior segment of the eye) is visible on the display. Align the device to the patient's eye by lateral adjustment using the joystick until:

- ❑ the image of the fixation point appears optimally focused in the green square on the display,
- ❑ the image of the cornea (right eye deflected to the left, left eye to the right) is free of reflections (system-related lack of definition), and
- ❑ the image of the anterior crystalline lens is visible in the pupil.

☞ **Note**
The image of the fixation point may not lie in the image of the lens or cornea!

Tips for anterior chamber depth measurement

If the device has been properly aligned, the images of the fixation point and the anterior crystalline lens will be simultaneously in focus, as they are approximately in the same plane.

As a rule, the image of the fixation point lies between the image of the anterior lens and that of the cornea if the device is optimally aligned.

☞ **Note**
The image of the fixation point should be near (but not in!) the image of the lens.

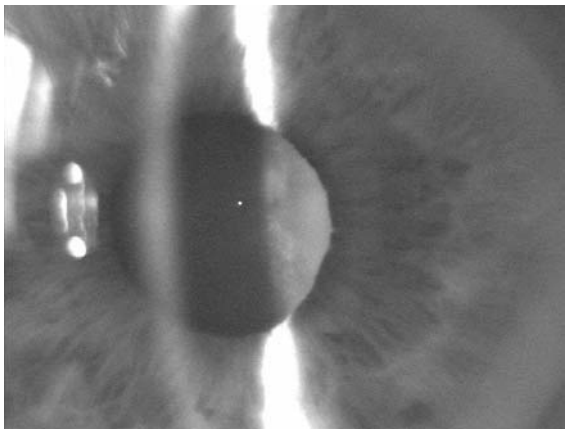


Fig. 69 Optimally adjusted optical section (lens with cataract)

Fig. 68 and Fig. 69 show optical sections of right eyes.

The patterns to the left of the corneal image are direct reflections of the luminous light exit aperture of the lateral slit projector. These reflections are not needed for the calculation of the anterior chamber depth. They must not affect the image of the cornea (see below).

At the left margin of the picture, additional reflections of the patient's surroundings (in this case a window) are visible. Depending on the lighting conditions in the examination room, the front side of the IOLMaster as reflected by the cornea may also be visible. These artifacts do not affect the measurement of anterior chamber depth, unless the significant image details (images of cornea and crystalline lens) and the image of the fixation point are eclipsed by this extraneous light. This may be alleviated by slightly darkening the examination room.

⚠ **Warning**
Failing to satisfy the above requirements for the measurement of the anterior chamber depth will either result in measuring errors or the measured values shown will be incorrect. Because of the complexity of the images measured, measuring errors may under certain circumstances not be recognised as such.
The IOLMaster must be adjusted very carefully for anterior chamber depth measurements.

The measurement of the anterior chamber depth on eyes with very small pupils (e.g. with glaucoma) is particularly problematic and needs some practice.

The anterior chamber depth of the human eye also depends on the accommodative state of the eye. This cannot be assessed from an optical section of the anterior segment.

☞ **Note**
It is advisable to measure accommodating patients under cycloplegia.

Measuring errors

The "Error" message may have two basic causes:

- ❏ The results of the five internal individual measurements vary by more than 0.15 mm (very rare), or
- ❏ the images produced (optical sections) do not contain relevant structures (normally without the edge of the crystalline lens) or disturbances are preventing their detection.

Incorrect settings

Defocused device

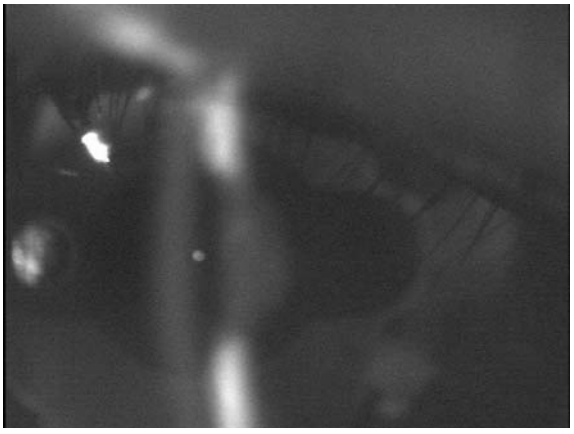


Fig. 70 Image of a strongly defocused device

Cause

If the device is not optimally focused, the image of the fixation point will be larger and fainter. At the same time, the images of the front edge of the lens and/or the cornea may become so faint that they cannot be recognised as such. In such a case, the system displays an "Error" message and an explanatory text indicates which image details are either missing or could not be recognised correctly.

Remedy

Improve the focus adjustment of the device and repeat the measurement. The fixation point must be optimally focused.

Tips for anterior chamber depth measurement

☞ **Note**
As a rule, slight defocusing of the device does not have a significant affect on the anterior chamber depth measurement.

Missing lens image with phakic eyes

Cause

Particularly in the case of eyes with small pupils, it is possible that no light is reflected back into the viewing optics of the device. A slight lateral misalignment may make the lens invisible. This problem may also appear with patients who are restless or fixate poorly.

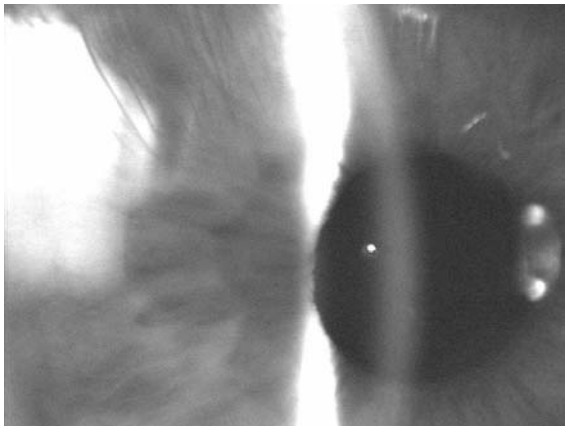


Fig. 71 Slit image on the iris (invisible lens)

Cause

In such a case, the slit image on the iris is (almost) continuously visible. The automatic evaluation software does not recognise this kind of maladjustment. The system will display values that are too short.
These values do not correspond to the actual anterior chamber depth, but represent the distance between the anterior cornea and the iris. The value displayed is not the exact reading for the anterior chamber depth!

Remedy

Adjust the device laterally until the anterior lens becomes visible. If necessary, ask the patient to look steadily at the fixation light. Then, repeat the measurement.

☞ **Note**
It suffices if a relatively small section of the lens is visible. The picture below shows an alignment which permits accurate measurement.

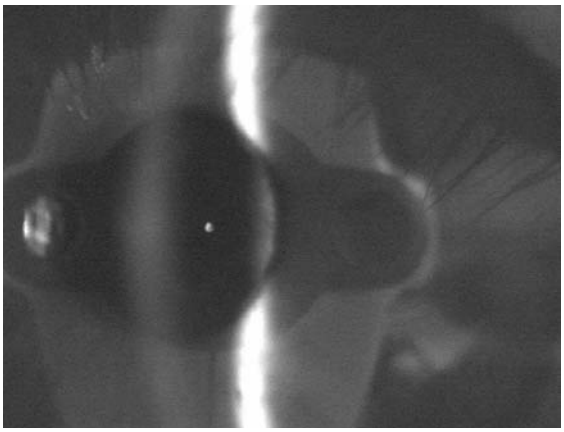


Fig. 72 Minimally visible anterior lens

This image is sufficient for the calculation of the anterior chamber depth. (In this photo, the front side of the IOLMaster is visible as a non-disturbing artefact).

Image of fixation point in lens

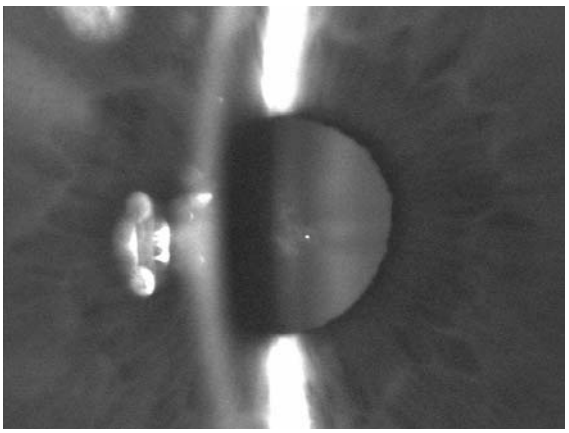


Fig. 73 Fixation point in lens image

If the image is laterally misaligned, the image of the fixation point may possibly lie within the lens image.

Cause

Position the device so that the fixation point lies between the images of crystalline lens and cornea. Then, repeat the measurement.

Remedy

Tips for anterior chamber depth measurement

Reflections in the corneal image

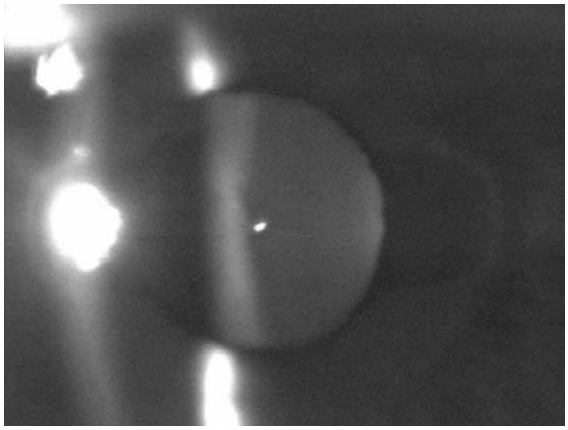


Fig. 74 Reflection in corneal image due to lateral misadjustment

Cause

The lateral adjustment of the device is not correct. Illumination reflections can be seen in the corneal image slit and the fixation point lies within the lens image.

Remedy

Adjust the device laterally until the corneal image is undisturbed. As a rule, the fixation point will then be between the image of the anterior lens and that of the cornea. Repeat the measurement.

Pathological findings

Dry eye

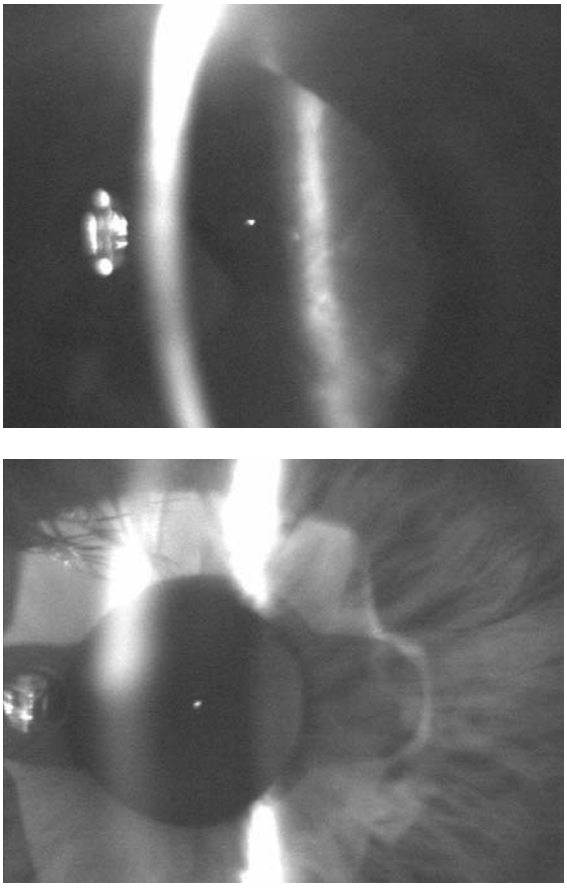


Fig. 75 Optical sections of dry eyes

Cause

A locally interrupted tear film considerably changes the scattering properties of the cornea. For this reason, the optical section of the cornea may become irregular.

Remedy

Ask the to patient blink several times to replenish the tear film on the cornea, then take the measurement immediately or use a tear supplement to prevent rapid drying.

Tips for anterior chamber depth measurement

Irregularities of the corneal surface (scars)

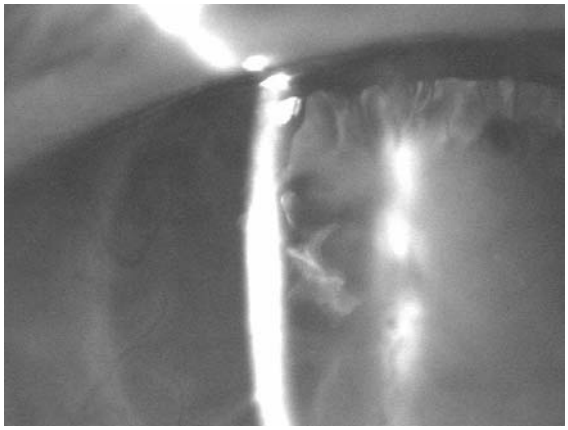


Fig. 76 Condition after keratoplasty (same eye as shown in Section *Tips for keratometer measurement*, Fig. 67, page 92)

Cause

Scars and local irregularities of the anterior cornea impair the image quality of the optical section of the cornea.
Depending on the extent and degree of these irregularities, this may lead to measuring errors.

Remedy

In such a case, the fixation point is imaged as a "cloud" and it is impossible to improve the adjustment. If apparently plausible anterior chamber depth results are nevertheless displayed, they can only be regarded as reference points.

Warning
To obtain reliable data, all the other known facts and findings of this eye should be included in the evaluation.

How to adjust the device

Ask the patient to relax and look at the yellow fixation light.

Focus on the iris, not on the light spots. Adequate room lighting will facilitate the detection of iris structures. Avoid direct exposure of the eye and device front panel to extraneous light.

In particular, ensure that the visible right and left edge of the iris is not disturbed by reflections from lamps and windows.

If the iris structure is not discernible, focus on the edge of either iris or pupil.

Serious defocusing will result in incorrect data.

After the image has been taken, the operator should check if the software has correctly detected the edge of the iris. If the circle segments drawn in the image do not define the iris correctly, the result must be discarded. Click on ***OK*** to confirm the results and save the data.

Troubleshooting

If the system fails during operation, take the following steps to restart:

- Switch on the power supply at the power switch (**1**, Fig. 9).
  An automatic test program will run before Windows is launched. Once this has been successfully completed, Windows and the device program will be restarted and work can be resumed.



Caution
Pulling the power supply plug or cutting off the power while the device is running may cause a loss of data and/or defects in the device's control software. However, no danger to the patient or user ensues as a result.

Update Installation

The following is a description of the installation of the software upgrade to version 5, as well as the calibration of the keratometer adjustment aid.

To install the software, carry out the following steps:

1. No USB device may be connected to the IOLMaster while the update software is being installed!
2. Switch the IOLMaster on.
3. Wait until all internal system tests have been performed and the Patient Manager appears.
4. Open the CD-RW drive on the left side of the IOLMaster and insert the update CD.
5. To launch the update procedure, click on **Setup** in the **Options** pull-down menu and select **Update**.
6. Follow the instructions on the screen. After installation the IOLMaster will be automatically shut down and then booted up again.
7. Remove the upgrade CD from the drive. Once the IOLMaster has booted up and a message prompting a check of the calibration appears, the software update has been completed.

If you wish to switch off the IOLMaster after the software update, click on the ***EXIT*** icon and confirm with ***OK***. Do not switch the IOLMaster off at the power switch until the cursor on the screen can no longer be moved using the touchpad (for IOLMaster with black power switch) or the screen is completely black (IOLMaster with green illuminated power switch).

Please check the current software version of your IOLMaster after restarting. For this purpose, click on **About IOLMaster** in the **?** pull-down menu.

After updating to version 5, patients already measured on the same day with version 4 cannot be re-measured. Patient measurements should therefore be completed before the update is carried out.
These patients can be measured with version 5 in a completely new session on the following day.

The mean value of single measurements taken with version 4 will continue to be displayed. The composite signal and composite reading are not determined here.

Calibration process for the keratometer adjustment aid (traffic light display)

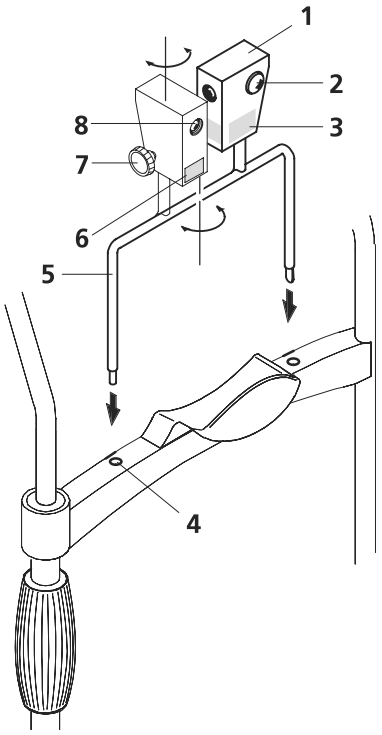
1. If the Advanced Technology Software version 5 has been installed on your device and you wish to use the keratometer adjustment aid (traffic light display), it must first of all be calibrated.
2. Switch the IOLMaster on.
3. Wait until all internal system tests have been completed and the Patient Manager appears upon confirming the calibration prompt with **OK**.
4. In the **Options** pull-down menu, click on **Setup** and use the **Program Settings** to display the **Program** dialog. Activate the **Adjustment aid** here (and **Automatic**, if you wish).
5. Create a new patient with **New**.
6. Change to keratometer mode by clicking the appropriate icon or pressing the **<K>** key.
7. Follow the instructions on the screen.

The test eye must be clean. If the test eye for the IOLMaster is not available, abort the calibration process with **Cancel**. The **Adjustment aid** will then be deactivated in the **Program Settings** dialog and can no longer be used.
If the software is unable to perform the calibration (message described under item 10 is repeatedly displayed), the cause may be inadequate room lighting. It is recommended that the front panel and test eye be shielded from direct or lateral light. The best results will be obtained when the examination room is slightly darkened.

8. Then you will be prompted to repeat the process once again.
9. If the calibration process was successful, a message to this effect will be displayed.

The keratometer adjustment aid (traffic light display) can now be used to position the keratometer at the optimum measurement setting.

10. If a message appears stating that variance between the calibration values of the two calibrations was too wide, the entire calibration process must be repeated from Step 7 onwards.



1 Test eye holder
2 Test eye for [ACD]
3 Set values and tolerances
4 Location hole
5 Asymmetrical holder
6 Set value and tolerance
7 Locking screw
8 Test eye for ALM and KER

Fig. 77 Setting up the test eye

Checking the measurement functions

After switching on the device will prompt a daily calibration check prior to patient measurements. Upon confirming with OK a check will be performed of measuring functions and work on the device can begin.

The test eyes supplied with the device (**1**, Fig. 77) are for verifying that the device is serviceable and properly calibrated. Measurements can be performed on these test eyes as with a human eye. Last, first name and date of birth are mandatory here as well! The supplied scale is to be used for checking the WTW value (optional).

Warning
The calibration must be checked every day before starting measurements on a patient. The measured values can be printed out and filed for documentation purposes. If the values obtained from the test eye are not within the given tolerances, no patient measurements may be taken! The device must be shut down immediately and secured against inadvertent use. Then notify Carl Zeiss Service.

- Insert the asymmetrical holder (**5**, Fig. 77) into the holes adjacent to the chin rest (the holding pins for the paper pads (**4**, Fig. 77) may need to be removed beforehand).

The test eye (**1**, Fig. 77) is secured by a locking screw and mounted on a mandrel which allows it to rotate (**7**, Fig. 77). The respective set value and tolerance (**3** and **6**, Fig. 77) for checking the calibration status are marked on the test eye (**1**, Fig. 77).

In the delivery condition a patient **!CHECK DEVICE!** with birth date 01/01/1911 has been entered. Because of the exclamation mark in front of the name, this "patient" will always be at the top of the patient tree in the Patient Manager and can thus be easily found every day.

- Highlight the patient !CHECK DEVICE! and click on ***NEW***.

Axial length measurement and keratometer

The test eye (**8**, Fig. 77), marked with AL, R, the respective set values and tolerances (**6**, Fig. 77) is used for checking the axial length (AL) and keratometer (R).
The measurements should be taken in the same way as for a human eye.

If the readings (in the case of the keratometer, the radius) are within the tolerances stated on the holder (**6**, Fig. 77), the device is properly calibrated.

Anterior chamber depth measurements

The (larger) test eye (**2**, Fig. 77) on the side of the test eye holder (**1**, Fig. 77) (marked with the ACD, set value and tolerance) is for checking the anterior chamber depth measuring device. The surface structure simulates the cornea. Before starting measurements it must therefore be clean and grease-free (wipe off with a dry cloth!).

- The measurements should be taken in the same way as for a human eye. On the video screen verify that the adjustment criteria for an optimum optical section are correct, as for measuring the ACD on the human eye (see page 50).
- Here again, if the measured values lie within the given tolerance, the anterior chamber depth measurement is functioning correctly.

Note
Although the side (right or left on the simulated eye) is immaterial for checking the axial length measurement and keratometer, because the beam path for the measurements is rotationally symmetric, it is recommended that the asymmetrical holder (**5**, Fig. 77) be reversed when checking the anterior chamber depth measurement and the check performed on the other side. When comparing right and left, however, care must be taken to ensure that in both cases the test eye (**2**, Fig. 77) is positioned exactly vertically in front of the device.

☞ **Note**
The test eyes are ideally suited to practising the operation of the IOLMaster.

The status of the **Test eye** is also reset each time a new patient (**<*N*>** or icon) is admitted.

Warning
If the test eye readings are not within the given tolerances, the device must be shut down. Notify Carl Zeiss Service.

Verifying WTW measurements (optional)

The WTW scale (optional) (**2**, Fig. 78) is for verifying the WTW reading.

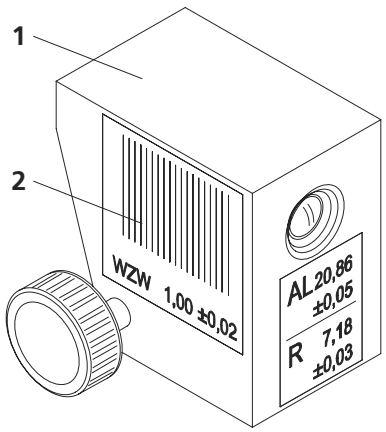


Fig. 78 WTW scale

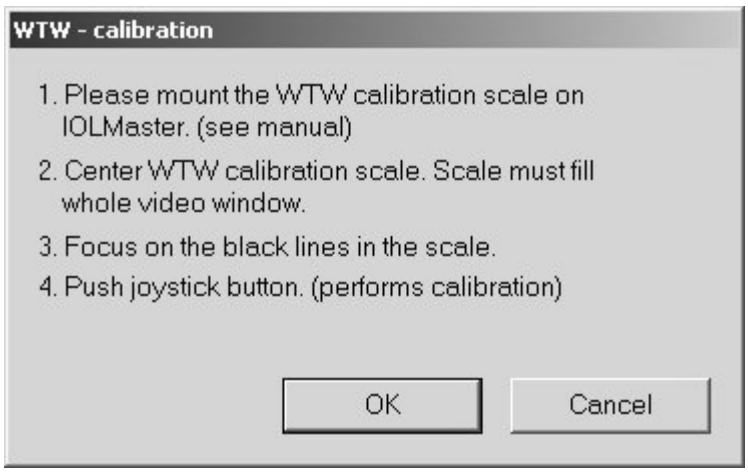


Fig. 79 WTW calibration

- Take a measurement.
  If the reading is within the tolerances, WTW determination has been properly calibrated.

Note
The WTW scale must completely fill the video window. The scale (black lines) must appear in focus.

Printer troubleshooting

Please use only printers recommended by Carl Zeiss Meditec. The printers currently recommended can be found at:
http://www.meditec.zeiss.com/iolmaster.
The printer models listed there have been tested in conjunction with the IOLMaster and provided the instructions for setting up (see page 19) are observed, the IOLMaster/printer system will operate reliably.

Should printing problems occur, delete all printer drivers not used.

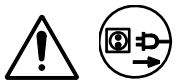
- Click on **Printer** from the **Options** - **Setup** pulldown menu.
- Select the connected printer and designate it as the standard printer (check the appropriate box in the **File** menu).
- Open the queue by double-clicking on the standard printer and delete all print jobs in the list by highlighting and pressing the ***<DEL>*** key.
- Select the printers not connected (except **New Printer**) and press the ***<DEL>*** key. Follow the instructions displayed on screen.
- Re-close the printer file once the unwanted printer drivers have been removed.

If the printer problem persists, notify Carl Zeiss Service.

If you connect a printer yourself, it may be connected to either the USB or LPT 1 parallel port. Please note that the printer must be compatible with Windows® XP (driver). To install, follow the instructions provided on page 19.

Care of the device

Warning
Before cleaning the device, switch it off and pull the power supply plug!



Caution
When cleaning, the greatest care must be taken to prevent moisture from penetrating the device or keyboard, as this may cause damage.



- ❏ All parts of the casing may be wiped off with a moist but not drip-wet cloth. Wipe off any marks or stains with distilled water, to which a drop of household washing up liquid has been added.
- ❏ Never use aggressive or abrasive cleaning agents.
- ❏ Use conventional cleaning cloths for wiping off the display and keyboard of computers and monitors.

- ❏ Contaminated parts with which the patient has come into contact during the examination (chin rest, forehead rest) should be cleaned with a disinfectant approved for the purpose. These parts are resistant to wiping off with low toxic agents (e.g. suds, quaternary ammonium compounds) and intermediate agents (e.g. alcohol, Javel water, iodine; classification pursuant to: Disinfectants and activity spectrum according to the Center for Disease Control and Prevention, Atlanta, USA).
- ❏ Remove dust from optical surfaces by means of a fine brush.
- ❏ If necessary, carefully clean these surfaces with a water-free ether/spirit mixture (9:1) applied with a cotton swab. The swab or lens-cleaning instrument should be moved with a circular motion from the centre of the lens to the edge. Ensure that the regulations for inflammable liquids are observed,
- ❏ To protect from dust, cover the system using the dust cover provided when not in use.
- ❏ Packaging materials should be retained for future relocation or repair or may be returned to the supplier as required.

Safety inspections

To ensure it remains in perfect operating condition, the device should undergo an annual safety check (visual inspection, protective conductor resistance and discharge current measurement). The safety checks must be carried out by an authorised specialist.

Please observe national safety regulations.

IOLMaster Basic Device

Dimensions (footprint)	390 mm x 300 mm
Height	max. 610 mm (headrest)
Weight	approx. 18 kg
Rated voltage; frequency basic device	 100 to 240 V AC (±10 %); 50/60 Hz
Power consumption basic unit	 90 VA
Earth conductor	Device should be connected only to sockets with an intact earth conductor
Protection class	I
Protection type	IP 20
Device type	B (DIN EN 60601-1)

Power isolation transformer

Rated voltage; frequency power isolation transformer	 100 to 127 V AC (±10 %); 60 Hz or 220 to 240 V AC (±10 %); 50 Hz
Power consumption power isolation transformer	 max. 115 VA (Total power consumption of connected external devices)
Power isolation transformer fuses	2 x T3.15 A H 250 V 5x20 IEC 60127 for 100 to 127 V AC 2 x T1.6 A H 250 V 5x20 IEC 60127 for 220 to 240 V AC

Environmental conditions for intended use

Temperature	10 to 35 °C
Relative humidity	30 to 75 %, no condenation
Air pressure	800 to 1060 hPa

Storage environment

Temperature	–10 to +55 °C
Relative humidity	10 to 95 %, no condensation
Air pressure	700 to 1060 hPa

Ambient conditions for storage and transport in original packaging

Temperature	–40 to +70 °C
Relative humidity	10 to 95 %, no condensation
Air pressure	500 to 1060 hPa

Measuring range

Axial length	
Area	14 to 40 mm
Resolution of display	0.01 mm
Keratometer	
Area	5 to 10 mm
Resolution of display	0.01 mm
Anterior chamber depth	
Area	1.5 to 6.5 mm
Resolution of display	0.01 mm
White to White (optional)	
Area	8 to 16 mm
Resolution of display	0.1 mm

Comparison/reproducibility

Comparison of IOLMaster measurements vs. conventional measurements of the human eye		
	Mean value of deviation	Standard deviation
Axial length*	-0.03 mm	±0.21 mm
Corneal curvature **	-0.01 mm	±0.06 mm
Anterior chamber depth*	+0.12 mm	±0.18 mm
IOLMaster reproducibility ***		
	Relative to standard deviation in human eye	
Axial length	±0.0256 mm	
Corneal curvature	±0.0129 mm	
Anterior chamber depth	±0.0334 mm	

* In comparison to precision immersion ultrasound instrument

** In comparison to manual keratometer[1]

*** Standard deviation (basic calculated simple standard deviation)[2]

[1] acc. to abstract "First experiences with a New Optical Biometry System" by B.A.M. Lege, W. Haigis

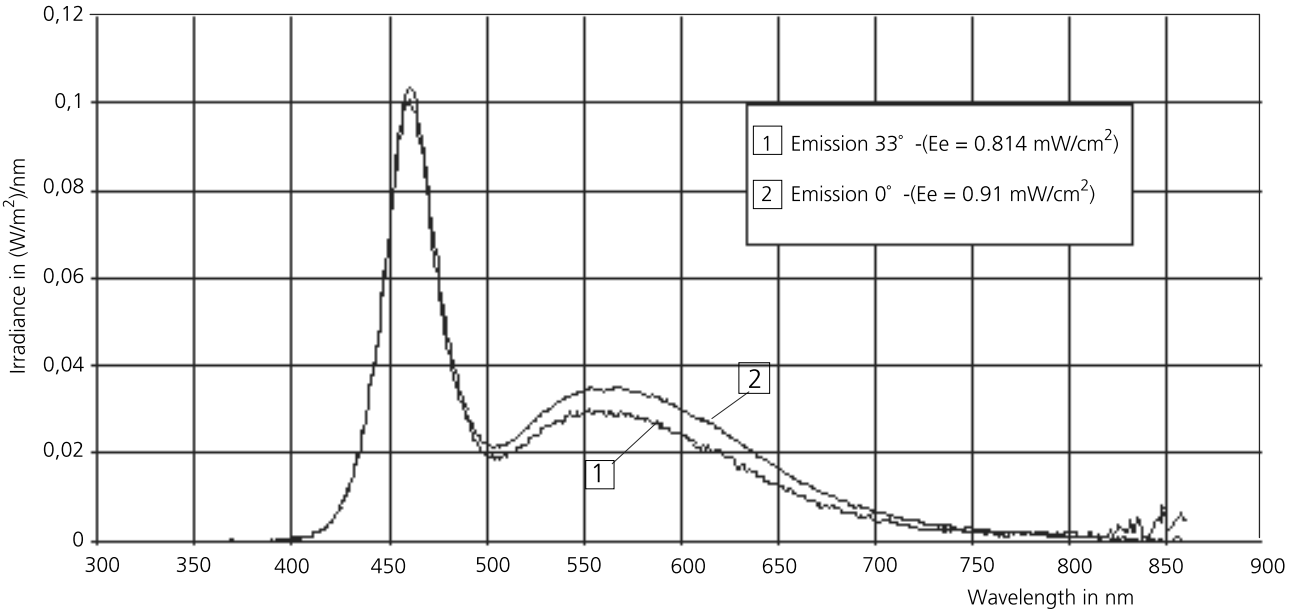
[2] cf. "Reproducibility of Measurement in Optical Biometry: Intraobserver and Interobserver Variability" by A. Vogel, B. Dick

Optical radiation

Light spots/WTW determination	
Source	LED
Wavelength	880 nm
Delivered power	< 100 µW
Axial length measurement	
Source	Semiconductor diode laser (MMLD)
Wavelength	780 nm
Max. power for measurement	450 µW
Max. power for alignment	80 µW
Measuring time for individual measurement	0.5 s
Pulse width	20 per eye and day
Number of possible individual measurements	1 (DIN EN 60825-1:2003)
Laser class	3B
Embedded (not accessible)	
Fixation light for keratometer and anterior chamber depth measurement and WTW determination	
Source	LED
Wavelength	590 nm
Delivered power	< 1 µW
Illumination for keratometer measurement	
Source	LED
Wavelength	880 nm
Delivered power	< 50 µW
Slit illumination for anterior chamber depth measurement, integral irradiance	
UV (300 to 400 nm)	0.00087 mW cm^{-2}
IR (700 to 1100 nm)	0.04 mW cm^{-2} (in spectral range of 860 to 1100 nm no detectable emission from light source)
L_B (phakic eye)	122.8 W $(m^2\ sr)^{-1}$
L_A (aphakic eye)	125.5 W $(m^2\ sr)^{-1}$

Spectral irradiance

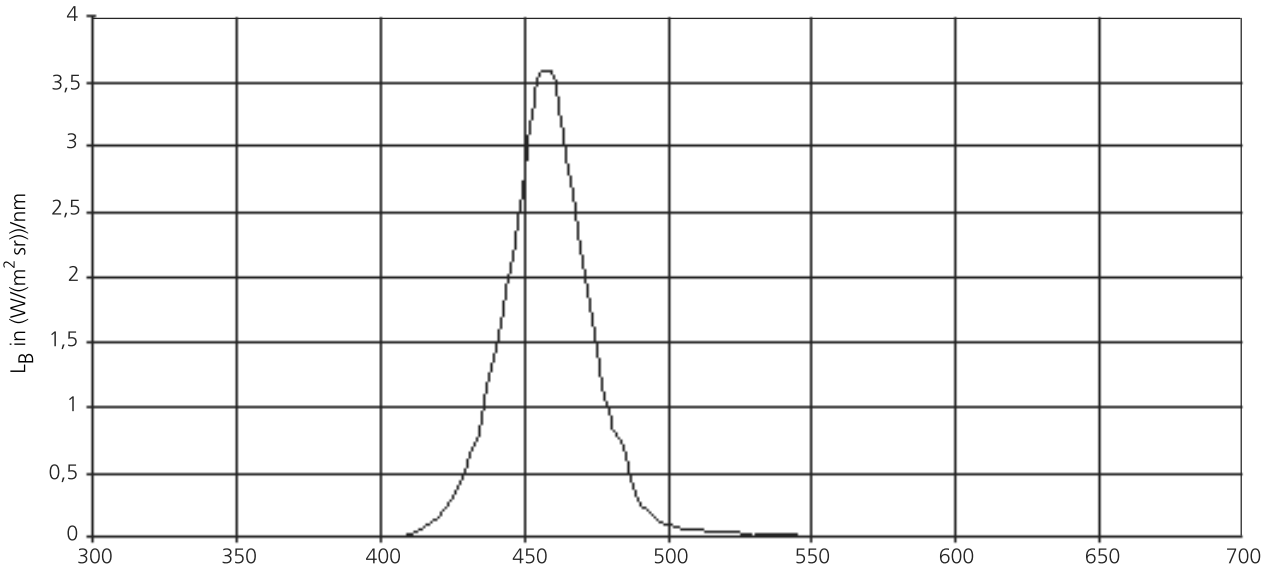
Spectral irradiance of slit illumination (white LED)
determined in the optical axis (0°) and at an angle of 33°



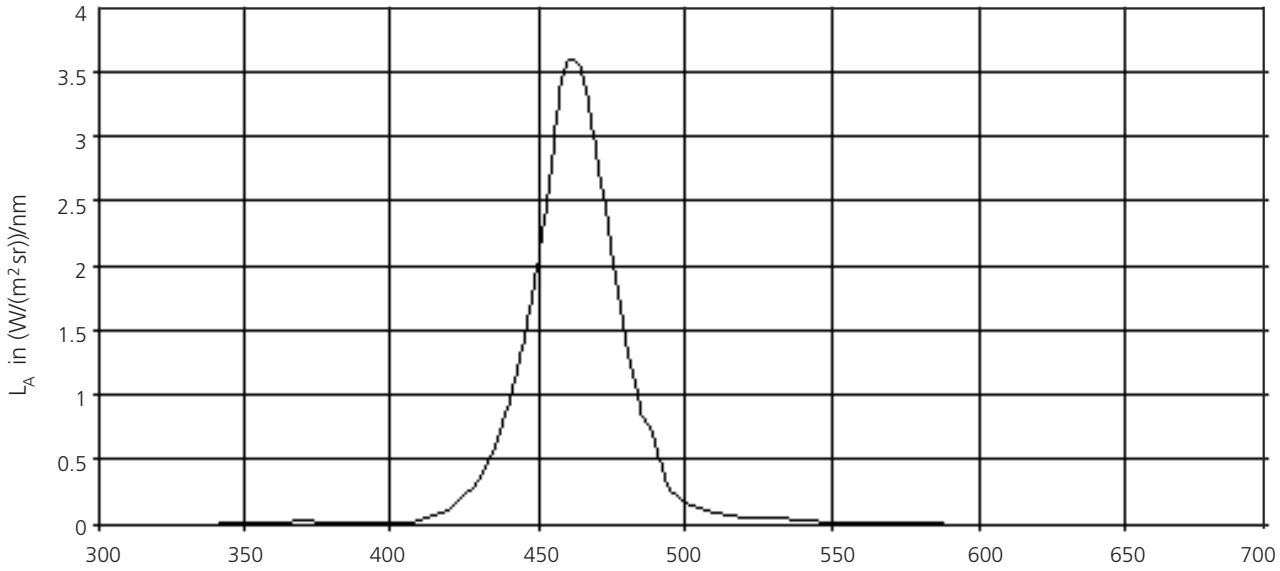
"Optical axis" or "0°" corresponds to the direct view into the illuminating projector.
33° is the angle for the intended use in anterior chamber depth measurement.

Spectrally assessed photochemical radiation densities

Photochemical radiation density of a light source (white LED - slit illumination)
for the phakic eye L_B = 122.8 W/(m² sr)



Photochemical radiation density of a light source (white LED - slit illumination)
for the aphakic eye L_A= 125.5 W/(m²sr)



The spectrally assessed photochemical radiation densities L_B and L_A are a measure of the risk of photochemical damage of the retina through light. L_B represents the measure for the phakic eye, L_A represents the measure for the aphakic eye or for the eyes of very young children. Readings of L_B and L_A in excess of 800 $W(m^2 sr)^{-1}$ are considered high. The radiation dose of the retina for a photochemical risk is calculated as the product of radiation density and exposure time.

The recommended radiation dose is based on calculations of the American Conference of Governmental and Industrial Hygienists (ACGIH) Threshold Limit Values for Chemical Substances and Physical Agents (Edition: 1995-1996).

The measured photometric values of the IOLMaster are far below the levels that are regarded as high. Thus, the risk of damage through optical radiation is extremely low. Nevertheless, anterior chamber depth measurement with the IOLMaster should be limited to the time absolutely necessary for the diagnosis. The risk of damage may be higher, if fundus photography of the patient to be examined has been taken within the last 24 hours.

Technical details and delivery packaging subject to change.

Manufacturer’s Declaration

CE 0297

The device meets the requirements of the Medical Device Directive 93/42/EEC and its national equivalent in the form of the German Medical Product Act (MPG).

Instrument class according to the Medical Device Directive: IIa

UMDNS No.: 18-014

If changes are made to the product or it is opened without the manufacturer's authorisation, this declaration will be rendered invalid.

ACD	Anterior chamber depth
ALM	Axial length measurement
C	Cornea
CD-RW	Compact disc rewritable
COM	Communication (serial interface for PC operating systems)
csv	Colon separated values (method of presentation in which the individual values have separators (semicolon, comma, etc.) in between them.
D	Dioptres (unit of measurement for refractive power)
DIN	Deutsches Institut für Normung = German Technical Standards Institute
EN	European standard
Fig.	Figure
HIPAA	American Health Insurance Portability and Accountability Act
ID	Identification
IOL	Intraocular lens
KER	Keratometer
LC display	Liquid Crystal Display
LED	Light emitting diode
mm	millimetres
MS	Microsoft®
MMLD	Multi-mode laser diode
µm	micrometre
OVM	Overview mode
PC	Personal computer
PCI	Partial coherence interferometry
SRK	Sanders Retzlaff Kraff
USB	Universal serial bus (standard interface for PC peripherals)
VGA	Video graphic adapter (video standard for PC with 640 x 480 pixels and 16 colours)
WTW	White to white distance



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